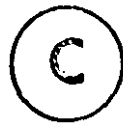


TREATMENTS FOR LOW BACK PAIN:  
A RANDOMIZED CONTROL TRIAL IN FAMILY PRACTICE

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## ABSTRACT

Many people suffer from some form of low back pain during their lifetime. A well designed morbidity study of general practice in England, using data collected from over 100 general practices, showed the incidence to be 1.6% per year and the prevalence to be 17.5% (62). Severe back pain may necessitate job changes or even job loss.

Forty-two million dollars were spent on industrial back injuries during 1974 in Ontario (86).

Review of the literature is hampered by the fact that only in a minority of cases can a diagnosis be made with any degree of certainty based on knowledge of pathophysiological mechanisms. Perhaps even less reliable is the chance that the doctor may know some therapy which will actually be superior to the spontaneous recovery rate. The spontaneous recovery rate is estimated at 70% after three weeks of symptoms (76). Because of the lack of progress in the area of diagnosis and treatment many studies lack methodological rigor.

This thesis attempts to examine and summarize some of the physiological, anatomical and mechanical factors that may be implicated in the etiology of low back pain and serve as a basis for rational therapy. It also reviews the encouraging advances in basic research which have taken place in the last decade.

In an effort to determine whether proven clinical outcomes occur, with certain standard treatment regimes, a randomized clinical trial is proposed to test the effectiveness of four different programs in a two by two factorial design. All participants will receive analgesics and/or anti-inflammatory agents at the discretion of their family physician. One group will receive no further treatment. The remaining three groups will have bed rest alone, bed rest with physiotherapy, or physiotherapy alone.

Baseline measurements will be obtained by objective methods of assessing spinal flexion, pain, and activities of daily living.

Prior to the commencement of the trial the study population will be divided into two prognostic groups by the method center based on the decision of the family physician to give the patient either major anti-inflammatory medication or minor analgesics.

It is expected that about 260 subjects suffering from low back pain will be identified by five groups of family physicians within a period of six months. For the patients receiving physiotherapy the same physiotherapist will visit each of the five groups two half-days a week in order to supervise the treatment. Compliance with medication will be assessed by pill counts.

Assessment of bed rest compliance will be measured by self-reporting, reports from a friend and a home visit.

One month after treatments begin, another family physician who is blind as to which group the patient is in will perform some of the

outcome measures. Outcome results will consist of relief of pain, return to work, return to normal activities, and relapse rate up to three months.

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1. INTRODUCTION

A patient who seeks therapy for pain in his low back will be entering his general practitioner's office for a diagnosis that can be made with any degree of certainty, based on knowledge of pathophysiological mechanisms, only in a minority of cases. Perhaps the only less reliable area than the diagnosis is the chance that the doctor knows of some therapy which will actually be superior to the normal spontaneous recovery rate.

Physicians, in general, don't like untidy diseases. Hilarie Hill perhaps summed it up best:

"Sir, backache is a bore to the patient and,

I suspect, to the doctor whom she consults" (41).

Against this background of unanswered questions in the diagnosis, the physician facing his patient is most reluctant or incapable of explaining his lack of knowledge, which makes it quite conceivable that most of these physicians turn towards some belief.

They believe in bed rest, analgesics and muscle relaxants or anti-inflammatory drugs and cold baths, in manipulation, in spinal fusion or in different types of exercises just to mention a few of the most commonly used recipes for low back pain patients.

This thesis will review in a critical manner the literature surrounding this ill-defined and poorly treated syndrome. In keeping with the main focus of the thesis the review is specially concentrated on medical therapies. After the review of the literature three intervention strategies will be developed in detail. Finally, a research design is presented for the testing of these strategies in a randomized clinical trial.

2. REVIEW OF ANATOMY AND PHYSIOLOGY OF THE BACK

2.1. FIRST SECTION (for individuals who feel they already have a superb knowledge of the anatomy and physiology of back pain).

Review:

The spine is a series of bones running down your back.  
You sit on one end of it and your head sits on the other.

Anonymous.

2.2 SECOND SECTION (for all the rest of us). (6,63).

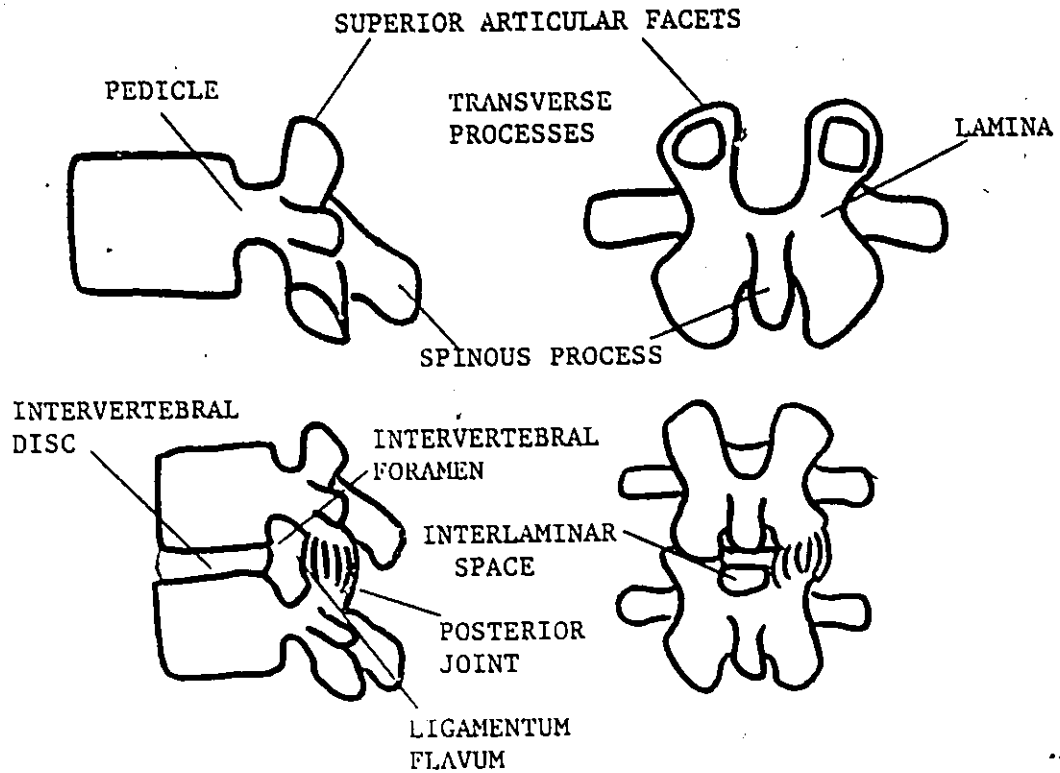
The main purpose of this discussion is to remind readers of the anatomical terminology and to correlate the gross anatomical features of the lumbar vertebrae with pathological changes of clinical significance.

Each vertebra has three functional components: the vertebral body, designed to bear the weight; the neuroarch, designed to protect the neural elements; and the bony processes, spinus and transverse, designed to increase the efficiency of muscle action. (Figure 1)



FIGURE I

Lumbar Disc Anatomy



The components of a lumbar vertebra; the body, the pedicle, the superior and inferior facets, the transverse and spinous processes, and the intervertebral foramen and its relationship to the intervertebral disc and the posterior joint.

The vertebral bodies are connected by intervertebral discs and the neural arches are joined by zygapophysial joints. On the surface of the adult vertebral body there is a peripheral epiphysial ring which acts as a growth ring in the young but as an anchoring ring for the fibres of the annulus in the adult. Within this epiphysial ring lies a hyaline cartilage plate. The intervertebral discs consist of an outer fibrous casing, the annulus, and an inner gelatinous material, the nucleus pulposus.

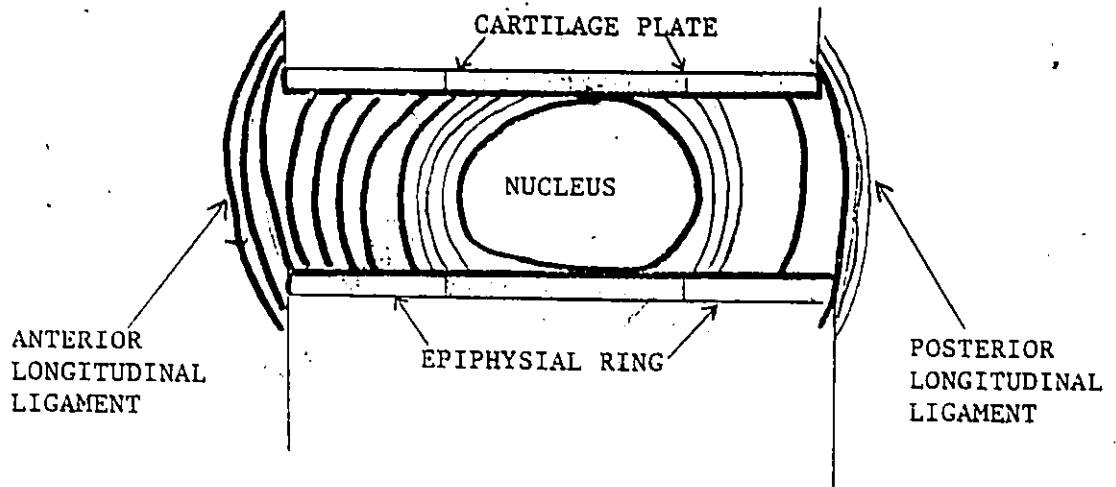
The anterior surfaces of the discs are strengthened by a powerful, anterior longitudinal ligament whereas the posterior longitudinal ligament only offers weak reinforcement. (Figure II)

As mentioned above, the neural arches are joined by zygapophysial joints and these are true synovial joints. In the lumbar area, facets are vertically parallel and their proper alignment demands a straight line. If the facets deviate in their direction of movement the articular surfaces are no longer parallel and friction or impingement may occur at some point in the normal gliding motion of these joints.

The joints are covered by a lax capsule but are reinforced by the ligamentum flavum anteriorly and by the supraspinous ligament posteriorly. However, the major resistance to movement in these joints is provided by the outermost fibres of the disc.

FIGURE II

Detail of Lumbar Disc



The spinal cord ends at L<sub>1</sub>. From this point all the nerve roots sheathed within the dura sac exit through the lumbar, sacral and coxalgia foramina. These nerve roots have several points at which they are in intimate contact with the intervertebral disc and therefore vulnerable to compression by pathological changes (Figure III).

Finally, the sacroiliac joint may, in the past, have been incorrectly thought of as the cause of low back pain. This appears to be unjustified on an anatomical and physiological basis. It has a very limited range of motion and has extremely powerful ligamentous supports.

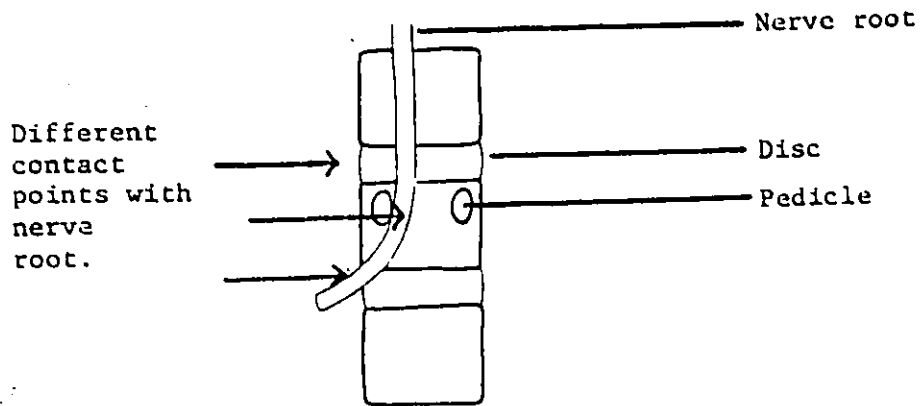
Likely the only time that these ligamentous supports relax is during the latter stages of pregnancy and this may in fact be the cause of low back pain at this time during pregnancy.

### 2.3 DEGENERATIVE CHANGES

The nucleus pulposus is a colloidal gel and in the young the nucleus is about 80% water. However, as the nucleus approaches the second or third decade it begins to lose its water-binding capacity for reasons which are unclear, but in this aging process there is a decrease in the protein polysaccharide with a loss of imbibition properties. Similar changes occur in the intervertebral disc by the third decade and it now loses its vascular supply and receives nutrition by diffusion of lymph. Finally, the elastic properties of the disc reside heavily in the annulus and the elasticity of the

FIGURE III

Sites of new root irritation



annulus decreases with advancing age and there is a relative increase in the percentage of fibrous elements. The disc therefore becomes less elastic.

The first stage of degeneration would appear to be at the attachment of part of the hyaline cartilage plate. This breaks the integrity of the annulus and the nucleus material can now escape between the vertebral bodies. It also permits abnormal movements to occur between adjacent vertebrae and the synovial joints may become malaligned or subluxed.

In summary, the nucleus pulposus acts as a ballbearing in flexion and extension and the vertebral bodies roll over this incompressible gel while the posterior joints guide and steady the movement. The annulus acts somewhat like a coiled spring, pulling the vertebral bodies together against elastic resistance of the nucleus. With degenerative changes, however, the nucleus may seep into the part of the annulus ring or on occasion may break right through it.

#### 2.4 MECHANISM OF PAIN

There are multiple possible sources of pain in the vertebral column. The synovial lining of the facets and the articular capsule of the joints are well supplied by sensory as well as vasomotor nerves. The annulus and the nucleus of the disc are felt to be insensitive to pain sensations.

The longitudinal ligaments are found to contain sensory nerve endings and they are specially prominent in the posterior longitudinal ligament. The muscles, of course, are well supplied with pain fibres and with muscle spasm these send off the appropriate message.

There is some controversy as to whether nerve roots themselves are capable of pain but most authors agree that if they are inflamed they can send pain messages.

Finally, the ligamentum flavum and the interspinus ligaments are felt to be nonsensitive as is the dura which surrounds the nerve sheaths.

### 3. A REVIEW OF THE LITERATURE ON LOW BACKACHE

#### 3.1 INTRODUCTION

The current scientific literature on low backache is enormous. Conservative estimate is one new article every 12 hours. With such a loosely defined diagnosis and management most health professionals feel that the disease falls into their particular domain. In the past decade the following groups have dominated the literature: orthopedic surgeons, physiotherapists, physiatrists, general practitioners, industrial physicians, acupuncturists, psychologists, and psychiatrists.

A view presented here comprises primary sources only. The majority of the references were obtained through MEDLARS searches and through bibliographies of authors of the more methodologically rigorous articles.

An attempt has been made in this review to assess the methodological merit of some of the cited articles. In line with the eventual study this assessment has been primarily focused on articles in general practice and therapy papers which are methodologically sound. It will of course be obvious from what was previously stated that most studies on back pain are of a descriptive nature, many are retrospective and few could be termed rigorous.



The review proceeds in the following fashion. First, a general overview of the literature is surveyed. It is in this section that issues such as incidence, prevalence, causation and prognostic factors are reviewed. Next, because the eventual study will take place in a general practice setting, a review of the contribution in this area will be categorized. Finally, a review of all the randomized clinical trials that have taken place in this area will be presented.

In order to provide clarity, tables will be included in each section.

### 3.2 INCIDENCE (TABLE I)

The word incidence is said to be one of the most generally misused terms in the medical literature. One commonly sees it used improperly either when prevalence rate is the appropriate term, or sometimes, when the quantity under consideration is not even a rate but just a raw count of the number of cases. Finally, in establishing the incidence rate there is always confusion in the literature with the denominator. For a true incidence rate the population at risk but free of the disease at the beginning of the time interval is the necessary count.

Kellgren published incidence figures after a random sample of an industrial town in south Lancashire, England (52). This survey in fact produced only prevalence figures for the population.

TABLE I  
INCIDENCE OF LOW BACK PAIN

AUTHOR AND REFERENCE NUMBER	SOURCE OF SAMPLE	NUMBER/PERCENTAGE
DILLANE (19)	His practice in England	24.2
General Register Office U.K., ..morbidity statistics in general practice...1974	> 100 general practices practices in U.K.	1.6%
BARKER (1)	His practice in England	20 (estimated)

In 1966 a true incidence rate was published on a general practitioner's office in England (19). He followed the recommendations set out by the General Register Office on the measurement of morbidity statistics. His results of the incidence rate of 24.2 attacks per thousand patient - years at risk were similar to the morbidity statistics from general practice published by the General Register Office in 1974 (62). Finally, a comparable figure was also found by a general practitioner in a survey of his practice in 1977 (1).

### 3.3 PREVALENCE (TABLE II)

As mentioned previously, Kellgren surveyed the rheumatic complaints in an urban population in 1953 in England (52). Combining his figures for disc prolapse, disc degeneration, and osteoarthritis of the low back one obtains a figure of 18.5% for males and 11.6% for females. Some of the best research from a methodological point of view has been done by Swedish physicians. Horal made a random selection from the city of Gothenburg and found a rate of 33.5% in patients who had not reported any back pain to the health service prior to the date of their assessment (47).

Benn and Wood attempted to estimate the size (9.7%) of the painful back problem from the patient morbidity statistics in 1975 (2).

On this continent, an elaborate probability sampling design was staged in order to assess the characteristics of the general population

TABLE II  
PREVALANCE

AUTHOR	REFERENCE #	SOURCE OF SAMPLE	%
KELLGREN	(52, 53)	Random survey of urban	18.5 males
		U.K. population (1953)	11.6 females
HORAL	(47)	Random selection from Gothenburg Sweden	33.5%
BENN & WOOD	(2)	Review of U.K. morbidity statistics	9.7% (estimate)
MAGORA	(64)	Eight different occupations in Israel	12.9%
Morbidity statistics (62) from general practice U.K. 1974		> 100 general practices in U.K.	17.5%

in a major city of the United States (83). Of the 1,135 persons included in this analysis, 18% reported being bothered with pain in the back.

Magora surveyed a number of different occupations in Israel and found a rate of 12.9% (64).

Finally, the Royal College of General Practitioners reported 17.5% in a study completed in the year 1970-1 (62,84).

#### 3.4 BASIC RESEARCH IN LOW BACKACHE

One cannot help but be impressed by the contributions of two countries to the problem of back pain. British physicians, as will be seen later, have contributed a lot to well-designed clinical trials. However, Swedish physicians, in addition to doing some sound trials have contributed an enormous amount to the understanding of the basic mechanisms of low back pain. The main Swedish contribution has been from Dr. Nachemson and his department of orthopedic surgery in Goteborg, Sweden (76,77,78,79,80,81,82).

In 1963 this Swedish unit was able to show that the nucleus pulposus of the normal and also the slightly degenerated disc act hydrostatically (79). A series of in vitro experiments have been conducted over the past decade. The impetus behind these experiments was the fact that although chemical factors may be important in the reduction of low back pain there was a growing body of indirect evidence that mechanical sources were equally or more important.

In 1963 Hirsch and others demonstrated that the nerve endings in the outer portion of the annulus fibrosus were free fibre-endings of the type associated with pain or pressure perception (42).

The lumbar spine in normal and abnormal spines has been studied by means of a pressure measuring instrument (79,82,81). This instrument is introduced into the center of various intervertebral disc, and the subjects are asked to perform certain movements.

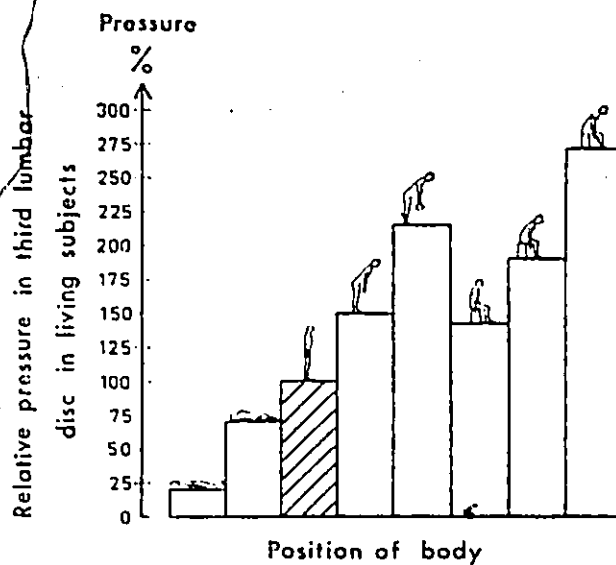
Figure V.

These studies showed that in the sitting position there were high intradiscal pressures and that there were high tangential stresses on the posterior part of the annulus. (It is known that 90% of all ruptures in the lumbar discs occur in the posterior part of the annulus) (79). The studies also showed that the intradiscal pressure was on the average 30% less in the standing position than it was in the sitting position and about 50% less in a reclining than in the sitting position. (Figure IV).

Valsalva's manoeuver generally increased the intradiscal pressure but the results were variable. The inflatable corset worn by some patients decreased the pressure in the examining disc by about 25%. It is hypothesized that the inflatable corset may substitute for the action of abdominal muscles by compressing abdominal contents to aid in transmission of forces to the pelvis (79).

FIGURE IV

Intradiscal pressure in different positions



Relative increase and decrease in intradiscal pressure in different supine, standing, and sitting postures, compared to the pressure in upright standing (100%).

Some of the patients had previously had posterior fusions (79). They were able to assess the fact that the fusion relieved the disc involved of about only 30% of its load.

As can be seen from the following diagram, other pressures in different positions and movements have also been observed. (Table III) (80,82) This table shows that many of the exercises which are currently being recommended by physiotherapists and physical medicine physicians increase the load on the lumbar spine to a magnitude often as high as those measured in the standing or leaning forward positions with weights in their hands. With regard to discal pressure, isometric exercises seem to be less dangerous. As will be commented on later under therapies, there are several control studies now which have tended to show that they have clinical benefit in therapy.

For many years exercises have been an important foundation in the treatment of low back pain based on the theoretical assumption that patients probably had weaker trunk extensors or trunk flexors. In 1969 Lindh and Nachemson measured the maximum instantaneous tension of spinal and abdominal muscles in 160 patients, approximately half of whom were suffering from a low back pain syndrome (77).

Statistical analysis showed that there was no difference in strength between the patients with back pain and controls, so there is no evidence that subjects with low back pain possess particularly



TABLE III

APPROXIMATE LOAD ON L3-DISC IN 70 kg INDIVIDUAL  
IN DIFFERENT POSITIONS, MOVEMENTS, MANOEUVRES AND EXERCISES

Activity	Load, kg
Supine	30
Standing	70
Upright sitting, no support	100
Walking	85
Twisting	90
Bending sideways	95
Coughing	110
Jumping	110
Straining	120
Laughing	120
Bending forward 20°	120
Lifting of 20 kg, back straight, knees bent	210
Lifting of 20 kg, back bent, knees straight	340
Bending forward 20° with 10 kg in each hand	185
Supine in traction (30 kg)	10
Bilateral straight-leg raising, supine	120
Sit-up exercise with knees bent	180
Sit-up exercise with knees extended	175
Isometric abdominal muscle exercise	110
Active back hyperextension, prone	150

weak muscles except as the study showed when they had been kept off work for a long period of time (>1 month).

Finally, some work has been done by Mohl and Wright to try to establish the normal range of spinal mobility (74). A pattern of mobility plotted against age reveals that after initial increase between the second and third decade, there was a progressive decrease with advancing age with spinal mobility being found to diminish as much as 50% between youth and old age. A considerable scatter of spinal mobility was demonstrated at each decade and the importance of regarding normal motility in terms of a wide range of values was emphasized. There was noted also a sex difference with male mobility exceeding female in anterior flexion and extension range but female exceeding male mobility in lateral flexion.

Chemical changes including a higher local acidity. A decrease in the proteoglycans and an increase in collagen occurred in degenerative states of the disc but so far we cannot successfully treat the chemical part of the disc syndrome (76). Since all the patients exhibit more pain when the spine is mechanically loaded, the knowledge gained from the disc-pressure measurement should provide a basis for successfully treating the mechanical part of the condition. (Table IV)

These intradiscal pressures have been confirmed by Japanese and Russian investigators (85,100).

In 1967 Nachemson with John Evans in Glasgow, Scotland, produced a paper measuring some of the mechanical properties of the ligamentum flavum and were able to show that the collagen-elastin ratio was such that the ligaments showed almost perfect elastic properties (78). In subjects with normal or moderately degenerated discs the ligamentum flavum has been found to pre-stress the disc by a force ranging from 1,500 grams in the young to 400 grams in the aged. It was concluded that the interlaminar ligament, at least in younger individuals, was able to create an intradiscal pressure of about 0.70 kilograms per square centimeter in the upright position. Therefore, in light of these findings it would appear that it is a highly specialized tissue protecting the nerve roots from mechanical impingement and also pre-stressing the disc providing some intrinsic stability to the spine (15).

Another area receiving intensive investigation is that of micro-fractures of the spine. This has been partly advanced because of a simple technique employing a stereoplotter. Binocular stereovision allows the apophyseal joints to be examined with greater precision than with conventional views. In seven patients Sims-Williams and others identified only one fracture on conventional film but fractures were seen on all seven using stereovision technique (98). The suggestion was that the fractures may have resulted from minor stresses in the bone with eventual fatigue failure. Similar findings had been reported as early as 1954 by two Canadian orthopedic surgeons (40).

### 3.5 ETIOLOGY (TABLE IV)

The foregoing discussion of etiology relates to basic research in the field. What follows will be more familiar to clinicians and will bring us up-to-date on a wide variety of factors. It is quite natural that a condition as common as this, with its unknown etiology, should be the subject of numerous speculations and theories regarding its origin. Although we still cannot rule out entirely structures other than the intervertebral disc and its surrounding ligaments, there is no definite proof that the condition stems from fasciitis, the muscles (myositis), the ligamentum interspinale, or even the intervertebral joints (degenerative arthritis, synovitis). That is not to say that these structures don't play some role in some patients with back pain, but nothing indicates their fundamental importance in the etiology of low backache.

Unfortunately, we also lack direct and conclusive evidence on the part played by the intervertebral disc, but there are a number of indirect indications that should be mentioned. MacNab (63) has stated that disc herniation is usually preceded by one or more attacks of low back pain. In his studies he also found that intradiscal injection of either hypertonic saline or contrast media often produced pain in patients of the same type as they experienced normally. It is not fully understood whether this pain is due to a increase in

TABLE IV  
SUMMARY OF FACTORS INVOLVED WITH ETIOLOGY

X-ray

Osteophyte collapse

PAIN/OR PRESSURE

receptor in outer layer of annulus possibly responding to chemical substances:

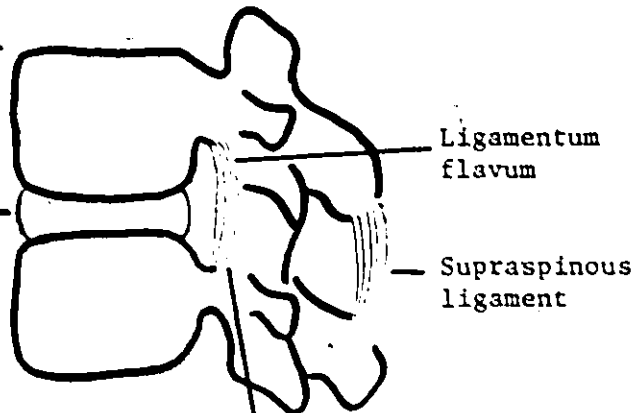
- hydrogen ions
- lactic acid
- histamine-like substances

HISTOLOGY

- 1) Fibrillation of nucleus.
- 2) Rupture of annulus.
- 3) Cartilage degeneration in end plates.

AGING

- ↓ Blood supply
- ↓ H<sub>2</sub>O content.
- ↓ Mucopoly saccharids.
- ↓ Collagen fibres.



"Gliding" posterior joint.

- ↑
- less hydrolic
- less stable joint.

intradiscal pressure or to chemical irritation, either of which could act on the outermost layer of the annulus where the nerve endings are located. (Inside the intervertebral disc proper, however, no nerve endings have been found).

Nachemson tied thin nylon threads to the fascia lumbosacralis, the muscles, ligamentum interspinale, the intervertebral joints, and ligamentum flavum and also the posterior part of the annulus, to the dorsal longitudinal ligaments and to the nerve root proper (82). These structures were irritated three to four weeks after surgery (surgery for sciatica) by pulling on the threads, but pain resembling that which the patient has experienced previously could only be elicited from the nerve root, dorsal longitudinal ligament or the posterior part of the annulus.

From pathoanatomical study it is known that radiating ruptures in the posterior part of the annulus are first seen around the age of 25 years. This is the same age at which low back pain syndromes start to be of clinical importance.

These facts, however, do not explain why older patients with osteoporosis and normal appearing discs have back pain. However, with the discovery of microfractures of subchondrally located trabeculae could be occurring in these older patients.

Radiological evidence of disc degeneration has been observed since x-rays first began to be used. Where osteophyte formation is a

prominent feature, the label osteoarthritis was first applied. (It is now reserved more for degenerative changes in the intra-articular joints). In fact Kellgren and Lawrence found evidence that the etiology of degenerative disease in the facet joints and discs may not be identical (52). In addition to x-ray surveys of discs there has been, of course, a large number of pathologists observing discs. At routine autopsies degenerative discs are found in 10% of person age 20 - 29 and there is an increase with age to 96% in those over the age of 60 years (58).

According to MacNab the relationship between abnormal x-rays of the lumbar spine and clinical conditions have always been overstated in the literature (63). There are, however, some definite radiological abnormalities that are often associated with low back pain. These have been summarized on Table V (82).

There are a number of important biological events which occur in the disc. MacNab has shown the loss of vascularity of the disc with the onset of adulthood (63). Histological examination of the disc shows fibrillation of the nucleus pulposus, rupture in the annulus fibrosis and cartilage degeneration in the end plates. Disc rupture may then occur as Hirsch noted that only 5% of all cases was a herniated disc responsible for the cause of the back pain (42,43,44).

A number of investigators have been working on the possibility of a chemical pain-producing substances as it is not likely that the

TABLE V

Radiological Abnormalities in the Lumbar Spine with Significance for Low Back Pain

<u>NON-RELEVANT</u>	<u>QUESTIONABLE</u>	<u>DEFINITE</u>
Single disc narrowing and spondylosis.	Spondylolysis	Spondylolistesis
Facet arthrosis, subluxation and tropism	Retrolisthesis	Lumbar osteochondrosis (Scheuermann)
Disc calcification	Severe lumbar scoliosis (>80°)	Congenital/traumatic kyphosis
Lumbarization, sacralization	Severe lordosis	Osteoporosis
Intraspongy disc herniation (Schmorl)		Marked multiple disc narrowing
Spina bifida occulta		
Accessory ossicles		
Mild-moderate scoliosis		



pain has a purely mechanical background. The pain substances discussed have been hydrogen ions, lactic acid, and histamine-like substances (59,65).

A number of chemical changes which occur with aging have now become well established (82). These include a decrease in the water content of about 80% to less than 65% and a decrease in the mucopolysaccharides with an increase in collagen fibres. These changes are felt to make the disc less of a hydraulic structure. This could lead to abnormal gliding which could then put strains on the adjacent ligaments and/or synovial joints.

Degenerative changes have also been noted in the intervertebral joints of the lumbar spine. However, these appear relatively late in life (43).

Back pain, of course, is occasionally caused by infection, tumors, fractures, osteoporosis, ankylosing spondylitis, rheumatoid arthritis, spinal stenosis and intra-abdominal or intra-pelvic disease. Such conditions occur in less than 1% of all cases in general practice (1,19).

With the advent of binocular stereovision the apophyseal joints have been examined with greater precision. Fractures in these joints are being seen much more frequently with this technique over normal radiological films. However the relevance of these fractures to

symptoms is still not clear. It has been suggested that they result from repeated minor stresses in the bone with eventual fatigue failure. As in other joints these fragments may form loose bodies which lie free in the joints or become secondarily attached to the synovial membrane. In fact, injection of an irritant fluid precisely into the apophyseal joint can cause referred pain indistinguishable from that associated with a prolapsed disc (63).

### 3.6 ETIOLOGY - THE ROLE OF TRAUMA (Table VI & Figure V)

The relationship of injuries to painful back remains unclear in the majority of cases. A number of studies and/or surveys have been conducted in the industrial and general population, but it is not unusual to see conflicting conclusions.

Clearly, severe trauma can injure a back. In general, if the intervertebral disc is healthy severe force will fracture the vertebral body but in the case of advancing degenerative disease of the disc severe force is more likely to rupture the annulus with the nucleus pulposus being displaced. Dillane in a survey of his general practice in London found that 7.9% of his patients gave injury as the cause of their low back pain (19).

A lot of work has been done trying to relate the patient's occupation with back problems on the hypothesis that heavy physical work would be more likely to bring on these conditions. However, direct comparison between occupation groups is often misleading

TABLE VI

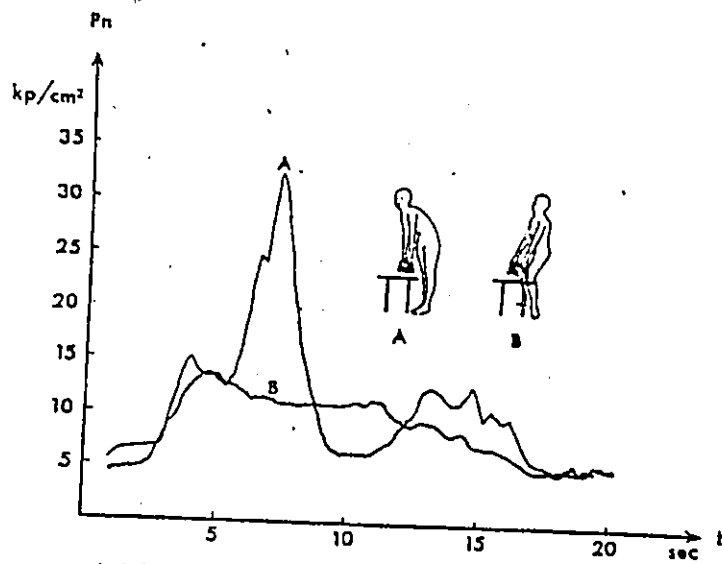
ETIOLOGY - TRAUMA

AUTHOR	SETTING	% GIVING HISTORY OF TRAUMA
DILANE (19)	General practice	7.9%
HOREL (47)	Random selection of general population in Sweden	27.9%
GLOVER (36, 37)	U.K. industrial plant	50. %
KERTESZ (56)	Canadian industrial (Workmen's Compensation)	70. %
BERGGUIST-ULEMAN (3)	Clerks and workers in Volvo plant, Sweden.	45. %

S

FIGURE V

Proper Lifting Techniques



Pressure recorded from the L3-disc in a 25-year-old male lifting 20 kg with bending of back and knees straight, with back straight and bending of knees ( $1 \text{ kp/cm}^2 = 1 \text{ kgf/cm}^2$ ).

because of the widely different age composition of these groups (53). In addition it is difficult to control for the increasingly well-known fact that people with illnesses tend to drift to lighter work initially, (a selection problem) rather than the work being the cause of their problem. Kellgren in 1952 was able to show that there was significant difference between miners and non-miners in the prevalence of osteoarthritis of the back (53). In 1953 they took a random sample from an industrial city, but in this case were unable to show statistically any significant differences between the prevalence amongst different occupations such as miners, tradesmen and domestics (52).

Hult investigated spinal disorders in several populations; children, teenage apprentices, woodsmen and industrial workers (48). A lumbar syndrome occurred in 52.7% among the light workers and among those with heavy labour the figure was 64.4%.

Another Swedish study done by Horel used a random selection from the National Health Insurance service at Gothenburg and ended up studying 243 individuals who were known to have low back pain were matched with 243 controls (47). The controls were matched with regard to sex, age, and the fact that they had not been sick-listed for back pain in the previous twelve years. Results at the time of physical examination in 1967 showed that a surprisingly high percentage of the controls, namely 66.5% had in fact had back pain in the past. The

subjects reported that the pain was caused by accidents in 27.9% of the patients with known back pain and 23.4% of the controls. Both mentioned heavy lifting in terms of similar percentages.

Unfortunately, occupation was not taken into account in this paper.

In summary, three points stand out. First, severe trauma can cause back pain (disc or fracture). Once established, back pain can be aggravated by heavy manual labour. Finally, manual occupation has not definitely been linked to backache.

There is also the problem of the reliability of a subject's own history. Multiple factors influence the reliability; lapse of memory, suggestion on the part of the interviewer and often the problem of monetary compensation for the complaint.

A lot of the literature in this area comes from industrial sources, Glover in 1960 reported that at least 50% of all attacks of low back pain are reported to start in connection with a minor accident or strenuous movement (36).

Ullman reported on a controlled prospective study in Scandanavia (3). In the study she reported 42% of her patients stated that the symptoms started during working hours and that in 45% of the patients the symptoms appeared in connection with a specific accident i.e. bending, twisting or lifting or sudden movement or a fall. In her study they were both office workers and plant workers of the Volvo plant. However, working conditions differed so much between

the two groups of employees that separate analysis did not justify any firm conclusions as to which vocational factor or factors are of greatest prognostic importance for determining the course of acute low back pain.

All injuries sustained at work in Canada become the responsibility of the Workmen's Compensation Boards of the provinces. Annually, about 12,000 claims are accepted in Ontario alone (86). Kertesz reported 25 Workmen's Compensation patients matched with non-Workmen's Compensation hospitalized patients with low back pain (56). The Workmen's Compensation group had a significantly higher incidence of sudden onset and precipitating factors. They had a significantly higher ratio in almost every other factor that was analyzed and one wonders about the effect that they were being paid at reasonably high percentage of their normal salary while ill.

Analysis of the occupations that predisposed to low back pain was carried out in Israel; a higher proportion of persons with low back pain were engaged in the physically more demanding occupations (64).

### 3.7 SACROILIAC DISEASE

A recent paper published in the Lancet by Davis, describes a radioactive scanning method of detecting sacroiliac disease in females (17). The authors state that the results support the

suggestion that sacroillitis is a common organic cause of low backache in women. It may be that general physicians are missing this cause of low back pain, but one wonders about the generalizability of the results since it was based on assessments of women presenting to a rheumatology unit.

### 3.8 EVOLUTIONARY SPECULATION

It is assumed that when man assumed an erect posture he placed additional stress on his cervical and lumbar spine and that is the cause of degenerative changes. However, dogs and cows, who remain quadrupeds, also suffer from degenerative changes in their discs (44).

### 3.9 WARM BATHS AND BACK TROUBLE

One physician writing in the Lancet reports a rather unique idea as to the cause of back problems (5).

Sir, - For many years I have believed that much so-called "back trouble" is self-imposed by the patient or imposed by his medical advisers. In the early stages muscle trouble near the spine can be caused by an exposure to cold, and treatment is by heat, including warm baths. This cure is worse than the disease; the bones at the base of the spine are bent at right-angles when sitting in a bath, and scores of muscles, ligaments, and fibres are stretched. The heat relaxes them further still, and muscles become sloppy and will not do their work of bringing the body upright.

I can remember when cottages and farmhouses had raised firegrates and ovens. If you stood with your back to the warmth on a winter's day you would be quickly cleared



away with a shout of "Ruin your back!" Few working people had baths in their houses, yet bags of cement, flour, meat, or coal weighing as much as 2 cwt. were handled readily by scraggy underfed workmen earning a few shillings a day. Slipped discs were never heard of. The same is true of gypsies who, though never dirty, never bath yet can easily lift very heavy weights. I have had men working for me who have liked their hot baths and are now in harness, and I know of two ladies with back trouble who were ordered baths by their doctor and are now similarly encumbered.

Could the rising incidence of "slipped discs" be connected with the demolition of old houses and their replacement by homes with bathrooms? I believe that it could, and that people who never used a bath are now using them to excess. For cleanliness, showers should be used if back trouble is to be avoided.

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Cheadle Hulme, Cheadle  
Cheshire.

ROBERT BURROWS.

3.10 PSYCHOSOCIAL CAUSE OF LOW BACK PAIN (Table VII)

The Lancet, 1973, had an editorial aptly named "Physiotherapy or Psychotherapy?" where it was reported on a traction study done in Oslo showing that there was clearly no difference between traction against simulated traction (26). Most patients in both groups described the traction as pleasant, which may well explain some of the popularity of this treatment. Although the editorial was mainly pleading for proper clinical assessment of treatments, it did suggest that almost anything you did for patients with back pain will be received favourably. This likely accounts for most of the placebo effects seen with the multiple different therapies available, few

TABLE VII  
PSYCHOSOCIAL FACTORS IN ETIOLOGY

AUTHOR AND REFERENCE	TYPE OF STUDY	AUTHOR'S CONCLUSION REGARDING PSYCHOSOCIAL
SARNO (94)	Descriptive study	Positive
WESTRIN (102)	Random samples from population. Analytic cohort study.	"could not be proved"
ROSE (89)	Case-controlled	more stress in back patients lives prior to onset of back pain.
GILCHRIST (35)	Descriptive study	more anxiety in patients who develop back problems.
BERGQUIST-ULLMAN (3)	R.C.T.	negative.
NAGI (83)	Analytic survey (random sample)	all sociodemographic and psychological factors positive.

of which have ever been subjected to experimental rigor.

The literature is, of course, well supplied with articles suggesting that in the opinion of the author in a substantial proportion of patients, back pain has a psychogenic causation. Sarno's article is fairly typical of a large group of physicians who appear to take advantage of the fact that the lack of knowledge on the etiology aspect and quickly state that if one cannot find any pathology, the symptoms must be psychogenic in origin (94). He presented data on results of 69 patients that he had given psychotherapy to and showed that especially for the tension group, but also for the conversion-hysterical type they all did reasonably well. There were no controls in this study.

Westrin approached much the same area with a much better designed study (102). From a random sample of individuals from the General Sickness Insurance in Gothenburg, Sweden, he selected 276 cases who had been absent from work for a period of greater than eight days during the year 1964 because of low back pain. Patients and controls were matched by sex, age and salary. Subjects were unaware of the purpose of the study and the investigators did not know of the subjects' group identity. Practically all the patients and half the controls claimed to have low back pain during the time when the study was made.

Correlation with mental disturbances was studied, but close connection between low back pain and psychiatric problems could not be proved.

Some differences were noted between the two groups. For example, more than 20% of the male patients and only 10% of their matched controls found no real satisfaction in their work. The authors concluded that this demonstrates that work conditions other than physical work alone can be important in the origin of low back pain. However, an equally good interpretation might be that if you are ill with back pain it is difficult to like your work.

A rather neat study was performed by Dr. Rose where he administered a questionnaire to 36 consecutive patients with back pain and an equal number of controls of the same age, sex and living conditions chosen randomly from his list in general practice in England (89). He was able to show, using a scale similar to Holmes and Rahe, that more significant events occurred in the lives of patients during the three months before presentation in general practice with pain in the neck or back than in a controlled group of symptomless patients.

Another general practitioner, Gilchrist, reported on a study related to psychiatric and social factors of low back pain in his own general practice population (35). He found in analyzing 1,499 patients that there was a greater association of low back pain with a history of psychological illness in men and women aged 35-45 and in women between

55-74. Most of these patients reported a long history of anxiety and there was very little to implicate back pain as a depressive equivalent. There are two comments to be made on this paper; first, more than association is needed to relate two events causally and second, the author was not "blind" in that he reviewed his own charts and made up his own mind as to who had low back pain and who had and what type of psychological diagnosis.

In an elaborate probability sampling of Columbus, Ohio a study exploring a large number of issues related to back pain, did show that measures of emotional and psychological difficulties are associated with persistent back pain (83). But association does not mean factors are related causally.

In Sweden, a controlled prospective study looked at acute low back pain in industry (3). Two of the factors they did concentrate on were psychological factors and social factors. They used a number of different measurement tools in order to assess psychological factors. But, the authors conclude that no firm conclusions about the importance of psychological factors or the mechanism of the causal association can be drawn from the results of this study.

In summary, there is likely very little argument that patients with chronic pain such as may occur in low back disorders are entitled to have feelings of anxiety and depression. What has not been proven is whether, as a general group, people with backache have any less, or

5

any more psychological disturbances than other people in the population. In addition no studies have been able to show the psychological cause of backache.

3.11 ECONOMICS OF LOW BACK PAIN (WORKMEN'S COMPENSATION BOARD)

In England, the National Insurance figures yield the fullest estimate of morbidity in the community in terms of person-days of disability. The estimate of 13.2 million days per year lost due to the painful back is by any standard a serious amount (2). It makes up 3.6% of all sickness and injury incapacity and is not inconsiderable compared with such major time-losers as bronchitis and emphysema (39 million days), influenza (26 million days), ischemic heart disease (17 million days). It constitutes a greater loss of time than strikes which for the same period were 11 million days. Comparisons of this sort have lead Cochrane to remark, hopefully somewhat provocatively, that "if strikes are a threat to the economy, the National Health Service must be a disaster (2).

Besides the one in every 28 days lost from work because of pain in the back, there is another large group who are not counted in that statistic. These are the housewives, the elderly and the retired. The number of people consulting their general practitioner and going to out-patient departments exceed the number of spells of sickness and injury, which shows that the National Insurance figures do not give us the whole story.

The National Morbidity Survey showed that backache accounts for about one-third of the consultations for diseases of the musculoskeletal system and connective tissue and about one in forty of all consultations with a general practitioner in England (62).

There was such profound and widespread dissatisfaction with the situation that the Department of Health and Social Services set up a two year study by a working group under Professor Cochrane in 1976 (104). When this committee was set up it was estimated that the cost would be 7 million working days and around 100 million pounds in sickness benefit in National Health System treatment. The report itself gives official statistics to indicate that more than 375,000 people a year experience a spell of certified incapacitation because of back pain, resulting in the loss of more than 11.5 million days from work. Financial cost to the country in lost output in the National Health Services is estimated at almost 300 million pounds. Because most married women and elderly are not represented in this data, the figures vastly underestimate the problem.

The Scandinavian figures are equally depressing. They estimate that probably up to 80% of all people will experience back pain to some extent during their active life and it is clear that back pain usually affects people in their most productive age group, namely 30-55 years. Back pain occupies a prominent position in

their statistics on sick leave, accounting for 10-15% of all lost working days in Sweden (3).

In Canada, all injuries sustained at work are the responsibility of the Workmen's Compensation Board for the provinces. In the province of Ontario alone there were 12,000 claims accepted by the Board in an average year (86). From these claims about 10% of the individuals are disabled longer than 6 weeks (103).

Costs are influenced by time lost from work but not all workers require the same time off work. In a steel plant in Hamilton where the employees "own" the plant, 90% of the back injuries never lose any time off work (34).

### 3.12 CLINICAL COURSE (TABLE VIII)

Low back pain has an extremely variable clinical course dependant upon multiple factors some of which are the age of the patient, the selection of the sample from the general population or from the hospital and finally whether monetary compensation is available.

Certain facts do however, surface from most of the studies. First, once a patient has had one episode of back pain he is likely to have another (3). Secondly, at least 50% of all people suffering from back pain never seek medical care (51,52). Finally, for those who do seek medical care 70% have a spontaneous remission within four weeks of having seen a health professional (3).



TABLE VIII

CLINICAL COURSE

STUDY	% DURATION OF PAIN	RELAPSE NO. OR RATE	MEAN AGE & RANGE OF ONSET
HOREL (47) (Sweden)	67.3 for 4 weeks 28.2 for 4-6 weeks 4.0 for 6-12 months 0.5 > 12 months		35 yr. male & female.
HULT (48) (Sweden)	70 at 4 weeks	30 to 70% report 3 or more recurrences	
BERGQUIST- ULLMAN (3) (Sweden)	35 at 4 weeks	- 1.3 median - 62% had 1 or more.	
SIMS-WILLIAMS (98) (England)	50 at 4 weeks		
DILLANE (19) (England)	84 at 4 weeks (estimate)		
GREENFIELD (38) (U.S.A.)	68.5 by 5 weeks	19%	
	39 in 4 weeks		

As noted in other studies, morbidity increases with age and reaches the maximum between 50-59 years, and then the lumbar spine symptoms rapidly decline (3,63).

The mean age of onset for both males and females was approximately 35 years of age (47).

For those patients who had only one attack of back pain, the mean age was approximately 37 years of age and for the patients who had recurrences the mean age rose to approximately 51 years of age.

Horel selected at random from the National Health Insurance of Sweden 243 individuals who had reported sick leave because of back pain along with an equal number of matched controls (47). The duration of symptoms for the patients with back pain was 67.3% for four weeks, 28.2% lasted between four weeks and six months and 4% lasted six months to a year, and .5% lasted more than a year.

Comparing Horel's study with Hult's we find that the recurrences are frequent and three or more episodes have been reported in 30-70% of afflicted patients (48, Table IX). Bergquist-Ullman reports on acute back pain in a Swedish Volvo plant amongst clerical staff and the workers (3). They documented the time of duration of back pain prior to the initial assessment. Eighty-three percent had their back pain for less than 3 weeks at the time of their first examination. Median duration of the symptoms was 9 days. The range however, was quite wide, being 1-86 days.

TABLE IX  
Recurrences

Number of recurrences of pain during one year of observation.

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No. of recurrences	0	1	2	3	4	5	6
No. of patients	83	56	37	23	8	6	4

---

Time between recovery from the initial episode and the beginning of the first recurrence.

---

Time (weeks)	0-2	2-4	4-6	6-12	12-26	>26
Number of patients	8	22	16	26	31	31

---

Bergquist-Ullman reported similar recovery rates to the other two Swedish studies of approximately 70% within two months, but got quite a bit lower at one month recovery rate of 35% (3). During the year she observed patients 62% had one or more recurrences. No patient had more than six recurrences in a year. (see Table VIII) The median number of recurrences was 1.3.

Also noted was the time between recovery from the initial episode to the first recurrence of pain. A median time for this first recurrence was 63 days (see Table VIII).

They noted another interesting fact in that the duration of the recurrences was shorter than the duration of the initial episode.

In a randomized clinical trial of therapies in the United Kingdom, which showed no differences in outcomes between manipulation physiotherapy, corset or analgesic groups, 54% of the patients were better at three weeks and 75% were better at six weeks (20). A trend towards improvement was noted in the corset group at three months.

Recurrence rates were reported but, as only 57% of the original cohort was available, these figures are likely not reliable.

Sims-Williams reported the results of a randomized controlled trial of mobilization and manipulation for patients with low back pain (96). This was a double-blind controlled trial to compare

mobilization and manipulation against placebo physiotherapy. No differences were noted in the final analysis of the trial. Details were not available in the paper to assess the duration of symptoms but personal communication with the authors reveals that approximately 50% were better at one month in both the treated and controls (97).

Finally, in two articles from general practice in England Dillon and Barker report on back studies in general practice (1,19). Unfortunately, Dillon's measure of the duration of the attack was the time between the first and the last office visit. This would underestimate the duration of the time. He obtained a figure of 84% of the patients better by four weeks time using this method. He did find that unlike all Swedish studies there was no significant variation in the duration of the attack by age (although there was a trend of 33% for patients under 30, 38% for those age 30-59, and 41% for those age 60). Finally, he reported that if there was objective evidence of nerve root pressure, the attack lasted significantly longer than if there was not.

Barker, in his survey of pain in the back and leg in general practice, reported that half his patients consulted only once and the others consulted twice or three times (1). Although the survey lasted two years, it is not possible to work out the recurrence rate in the manner in which this data is reported.

In the U.S.A. Greenfield reported 68.5% improvement within five weeks, with a 19% relapse rate (38). These figures come from 419 patients who attended a walk-in clinic at Kaiser Permanente in California.

Duration of back symptoms, of course, varies depending upon the source. In the case of industrial populations with evidence of disc protrusion approximately 39% of men are back to work within four weeks (4).

### 3.13 PERMANENT DISABILITY

In general practice, less than 1% of all back pain is due to disease which might cause permanent disability or death (1,19). Even in the area of low back pain in working men receiving Workmen's Compensation, 90% of patients are able to return to work within six weeks of their injury (103). White completed a fascinating study on 568 patients with discogenic low back pain who were interviewed every six months for four years following their discharge from the Workmen's Compensation. Two years would seem to be a critical period in prognosis, whether conservative or operative treatment was used. Those who regained ability to work by this time were likely to retain it; those who failed to do so were not likely to improve sufficiently in the following two years. Several other points are worth mentioning from this study in that achievement of a satisfactory status was not

influenced by radiological evidence of congenital or developmental abnormality, degenerative change or instability of the low back spine.

In addition, achieving satisfactory status was unrelated to occupation and age was seen to have little influence on progress.

### 3.14 AGE AND CLINICAL COURSE

In an interesting retrospective study done by an orthopedic surgeon, 259 patients over the age of 50 were assessed for etiology (31). Systemic disease, particularly cancer, was much more prevalent in the older group. It was demonstrated that simple screening consisting of an ESR and serum concentrations of alkaline phosphatase and calcium and phosphorus would identify all cases of unsuspected malignant disease. (At least one of the values was abnormal in every case).

### 3.15 RANDOMIZED CLINICAL TRIALS

A randomized clinical trial is the best design to investigate treatment effects. The key feature of this design is that the experimenter has control over which group, treatment or control, that the subject is assigned to. The subjects are assigned on the basis of a random number format, either from a random number table or generated on a random basis by a computer.

Although random allocation of patients to the groups in the trial is the essential feature of a randomized control trial, there are nevertheless a number of methodological standards which must be met by

the trial in order to strengthen the validity of its conclusions. A summary of these criteria has been discussed by Sackett, and will be reviewed here (90).

### 3.15.1 Criteria for inclusion into the trial:

The study must describe what types of patients have been included and other important factors about them such as their location and situation. This criterion allows future investigators to generalize results or set up similarly designed experiments in order to test the validity of the results.

Included in these criteria are the patients' description of who was included in the trial and who was excluded.

### 3.15.2 Random allocation:

This feature avoids conscious or unconscious bias on the part of the experimenter in terms of which patient gets in what group. Stated in different terms it allows the group to be "comparable".

### 3.15.3 Prognostic stratification:

The experimenter may know that certain sub-groups vary in their risk of the outcomes. For example, if it is known that smokers are a greater risk for the outcome, the investigator should stratify smokers before randomization procedure so that the treatment and the control groups have an equal number of smokers.

Prognostic stratification should be reserved for factors which are strongly related to the target outcomes, otherwise the investigator may get into a position where he is stratifying numerous mildly related



factors and during the analysis may find that he has so few numbers in his cells that his analysis is not accurate.

Patients, of course, who enter the trial may have diseases in addition to the one which the trial is examining. One must make sure, for example, in a low back pain trial that patients do not have non-related muscular skeletal disease which could affect their participation or assessment.

\* Sometimes these co-morbid conditions may have a very strong influence on the outcome and so must either be handled by prognostic stratification or exclusion from the trial.

Finally, it is possible to do prognostic stratification during the analysis stage in certain circumstances (30). This likely should be reserved for situations where the investigator finds a confounding factor after completing his trial and wishes to distribute it equally between the two groups during his analysis. The investigator takes the risk here that he can in fact balance the two groups with the sample which has occurred in his particular trial.

#### 3.15.4 Description of the Therapeutic Manoeuvre:

In some ways this is similar to the criteria for inclusion in the trial in that the investigator must present enough detail of his manoeuvre, to allow readers to replicate the trial if they wish to.

#### 3.15.5 Compliance:

This issue has been ignored by medical designs for many years and is critical in the assessment of any trial. One must know

how well each of the groups followed the treatments given them in order to assess properly the results of the trial.

#### 3.15.6 Co-Intervention:

This term means that the experimentors must insure that both the controls and the group receiving the intervention have equal attention paid to them throughout the trial. Any additional therapeutic or diagnostic procedure applied to one group and not the other might effect and falsify the results.

#### 3.15.7 Contamination:

This is an attempt to minimize the control group getting the same or a related therapeutic manouevre as the treatment group in some form of external source. For example, in the back pain trial patients, of course, can go to osteopaths or chiropractors and receive related therapeutic manouevres.

#### 3.15.8 Diagnostic Criteria:

Whatever measurements the experimenter is using for the outcome should be consistent and reproduceable. This allows other investigators to use these outcome measures in other trials.

#### 3.15.9 Total Mortality Reporting:

It is important to report all causes of mortality in an experiment which uses this as one of the end points. This is to prevent the conclusion that although the treated group had fewer mortalities for one reason it increased the mortality of the same group through another mechanism.

As Sackett states, it is unlikely that any randomized trial will fully fulfil all these nine standards, but each trial should be assessed using these criteria to determine whether it has been given the best design within the limitations of design or the experimental setting.

### 3.16 TREATMENT (TABLE X)

A wide variety of treatments are available with the objectives of reducing or eliminating the patient's pain and returning him or her to normal daily activities. In line with the design of this thesis, which compares medical therapies, surgical therapies will not be commented upon in as much detail.

In general, the best efforts at trying to elicit which therapies are the most effective, come from the Scandanavian and British literature. These countries have been especially strong in trying to assess the effectiveness of traction, massage, mobilization, manipulation, and exercises.

#### 3.16.1 Traction:

Two trials in traction will be reported. The first one done by Lindstrom in 1970, with selected patients from an orthopedic out-patient clinic who had had back pain plus sciatic pain for more than one month's duration (60).. People with obvious disc prolapse were excluded. Sixty-two patients were randomized into three treatment

TABLE X

LOW BACK PAIN - TRIALS OF THERAPIES

AUTHOR/ REFERENCE	SOURCE OF SAMPLE	RESULTS	STATISTICAL SIGNIFICANCE OR TRENDS	MAIN METHODOLOGICAL PROBLEMS
H. Sims-Williams (96) R.C.T. (N=94)	Patient's G.P. had requested x-rays.	ONE MONTH: Active physiotherapy and (mobilization and manipulation). (Haitland Tech- nique) and traction, better than placebo physiotherapy.	$\chi^2 = 3.56$ $0.01 > P > 0.05$	<ol style="list-style-type: none"> <li>1) Open ended exclusion criteria available to physiotherapist.</li> <li>2) No justification for sample size.</li> <li>3) Subjective assessment of pain.</li> <li>4) Postal questionnaire used as assessment at 12 months. No comments on reliability or validity.</li> <li>5) No comments on compliance, co-morbidity, co-intervention or contamination.</li> </ol>
D.P. Evans et al (27) Cross-over (N=32)	rheumatology clinic	THREE & TWELVE MONTHS:  Patients given rotational manipulation (3 times a wk.) Group receiving therapy first, better at day 21.	No statistical differences. No trends.  at 4 weeks  $P < 0.05$ Wilcoxin test for pair differences	<ol style="list-style-type: none"> <li>1) Subjective assessment of pain.</li> <li>2) No sample size justification.</li> <li>3) No comments on compliance, co-morbidity, co-intervention or contamination.</li> </ol>
Doran et al (20) R.C.T. (N=456)	rheumatology clinic	No differences between 4 groups: manipulation, physiotherapy, corset or analgesics.	No statistical differences. At 3 months, trend to corset. (83% vs 65% vs 74% vs 76%)	<ol style="list-style-type: none"> <li>1) Overly rigid exclusion criteria.</li> <li>2) Multicentered trial at tertiary care level subject to referral bias, Berkson's bias.</li> <li>3) No standardization of manipulations or physiotherapy.</li> <li>4) High drop out rate. 40% out of 68 by three weeks.</li> <li>5) Total sample down to 75% at six weeks</li> <li>6) Questionnaires: reliability or validity not stated.</li> </ol>

TABLE X

## LOW BACK PAIN - TRIALS OF THERAPIES (continued)

AUTHOR/ REFERENCE	SOURCE OF SAMPLE	RESULTS	STATISTICAL SIGNIFICANCE OR TRENDS	MAIN METHODOLOGICAL PROBLEMS
Coyer (13) R.C.T. (N=146)	Unknown	Manipulation (Cyriax method) better than bed rest and analgesics.	Not done by Coyer. Completed by author (Gilbert) P=.006 at 3 wk. period. But P=.33 when 16 patients drop out in the bed rest group counted as successes.	1) Poorly defined exclusion-inclusion criteria. 2) Not a true random allocation ("alternate"). 3) No statistical analysis. 4) No comments on compliance with bed rest.
P. Hume Kendall (54, 55) R.C.T. (N=47)	Physical Medicine patients.	Isometric exer- cises better than mobilizing or extensor exercises.	Author states statistically significant difference, but no value given.	1) Small sample size with no justification. 2) Exclusion criteria not stated. 3) Subjective outcomes.
J.R. Glover et al (37) R.C.T. (N=84)	Factory workers in U.K.	No difference between rotational manipulation (15 min.) and placebo diathermy.	Trend: patients, in whom first attack lasted less than 7 days at the time of treatment, had less subjective pain with manipulation.	1) A unusual exclusion criteria leading to severe sample depletion (200-84). 2) No sample size justification. 3) All outcomes subjective. 4) No data on compliance, co-morbidity, co-intervention.
Lindstrom et al (60) R.C.T. (N=62)	Orthopedic clinic	A combination of intermittent traction, isometric exercises of abdominal and hip extensors is better than a combination of hot packs, massage and mobilizing and strengthening exercises. It is also better than hot packs and rest.	$\chi^2-13.70$ P<0.01	1) Improper selection: orthopedic surgeons choice cases from their clinics. 2) Possible problem with easily broken code procedure. 3) Subjective outcomes. 4) No sample size justification. Small numbers in each cell.

TABLE X  
LOW BACK PAIN - TRIALS OF THERAPIES (continued)

AUTHOR/ REFERENCE	SOURCE OF SAMPLE	RESULTS	STATISTICAL SIGNIFICANCE OR TRENDS	MAIN METHODOLOGICAL PROBLEMS
H. Bergquist- Ullman et al (3) R.C.T. (N=217)	Volvo clerks and workers.	Back school educational program and combined physio- therapy (Cyrilax and Janda methods; stabilization, gapping, articula- tion, stretching) were better than placebo shortwave.	Statistical significance for: a) sick-leave duration. b) duration of symptoms from first treatment.  NO statistical differences for: a) pain index (no trend) b) recurrences (Trend in favour of placebo).	1) No sample size justification. 2) Compliance, co-morbidity, co-intervention and contamination not assessed.
H. Weber (101) R.C.T. (N=72)	Orthopedic clinic.	"Tru-trac" traction is no better than simulated traction.	No statistical difference.	1) Only English abstract from Norwegian available.
J. Baldwin (73) R.C.T. (N=180)	General population in Scarborough	Mobilization no better than traction. Both had educational package.	No statistical difference. No trends.	1) Attrition rate 26%. 2) Majority of outcomes subjective.

groups, conventional physiotherapy, (hot packs, massage, mobilizing and strengthening exercise of the spine) control group of hot packs and rest and thirdly intermittent pelvic traction, isometric muscle exercises and immobilization. Results according to the author show that the pelvic traction and isometric exercises was the best treatment and reached statistical significance. The problem with the trial is that later on in the results section the author analyzing "the different methods separately" found there was no significant difference between the control and the traction group. In fact it is difficult to draw conclusions from the study because the actual numbers spread amongst the three treatment groups are very small and in fact in four places he had zero numbers in some of the cells.

In 1973, Webber placed 72 patients who had evidence of back pain and nerve root irritation into one of two groups (101). Either Tru-Trac intermittent traction, or a simulated traction. Results show there was no clear difference between the two groups. Most patients in both groups described the traction as pleasant, which may well explain some of the popularity of this treatment. A randomized control trial between mobilization and traction by Baldwin failed to show any differences between treatments (73).

Nachemson has shown experimentally that the pressure of the nucleus of the disc falls during the traction in the supine position by 25% (77). However, this experiment was done with normal subjects

with normal discs, and the comparison with the disease situation is questionable. In fact the concept that a protrusion will simply slide back spontaneously because of an increased space between the vertebrae, or that reduced pressure to the disc will have a suction effect, seems too mechanical in light of the complex pathology of disc degeneration.

### 3.16.2 Physiotherapy:

MANIPULATION - perhaps no area of therapy has caused as much controversy as this particular one. This is because several different disciplines use the method called manipulation and there is a long-standing animosity amongst them. Part of the problem results in the fact that there are many "manipulation schools" in the world. One is run by osteopaths, one by chiropractors, and physiotherapists have several of their own. All these used different methods of applying twisting, stretching and bending forces to the lumbar spine. The unproven theory behind most of these manouevres is that a "locked" and painful segment should be loosened. A diagnosis of this decreased segmental mobility was made by careful palpation through more or less thick layers of soft tissue. Various better designed trials using manipulation will be reviewed next. One cannot help but come away with the conclusion that if the clinical effect of these methods is superior it hasn't been shown in a form which would be reasonable for most clinicians who have a critical attitude.



In 1955 the British Medical Journal reported on a controlled study treating low back pain with manipulation in one group and bed rest and analgesics in the other group (13). The method of manipulation was that of Cyriax. There are a number of methodological problems with this study, the first one being that there was no randomization of patients to each treatment group which could form a considerable bias. Secondly, of the original two groups the control group lost 16 patients and in the analysis it was assumed that none of these patients became well (the correct assumption would be that they all became well). Nevertheless, the author went on to say that manipulation was more effective, although when his results are reanalysed (by me), including adding the 16 patients in, there is no significant P value obtained.

Glover in 1960 described a back syndrome where there was a clearly defined area of hyperesthesia and a local tender spot associated with the hyperesthesia (36). The final two points of the syndrome were dull ache in the same area and a limitation of movement by pain. After selecting the cases out of the engineering firm he manipulated the low back until a definite click was heard and claimed 89% success rate.

In 1974, Glover conducted a therapeutic trial in engineering works in England in which he randomly allocated patients to one lumbar rotational manipulation session of fifteen minutes followed by four

daily detuned short-wave diathermy sessions (37). The control group was given the detuned short-wave diathermy only. At the end of seven days there was no demonstrable difference between the two groups. The author felt in retrospect that he should have given more manipulation sessions.

In 1975 Doran released the results of a multicentred trial of 456 patients who had been randomly allocated to four treatments - manipulation, physiotherapy, corset, or analgesics (20). Conclusions were that there were never any important differences among the four groups of patients. However, he managed to keep track of only 73% of the sample to three months and by one year had only 57% of his sample. The technique of manipulation was at the discretion of the manipulator. A minimum of two treatments per week was given with an average of six treatments per patient. There was a barrage of letters to the editor. Cyriax himself wrote in complaining that the wrong type of patients were studied (15). The B.A.M. (British Association of Manipulative Medicine) group were particularly incensed with the B.A.R.R. (British Association of Rheumatology and Rehabilitation) trial because they felt that the B.A.M. members had not been given proper control over the admission of the patients to the trial (24). This appears to be one of the main points of controversy; one group claiming there are definite criteria for doing manipulation and insisting that these be used prior to the start of the trial.

In 1978 Sims-Williams studied 94 patients in a randomized control trial which included random allocation to active or placebo physiotherapy (96). Patients were selected from cases that the general practitioner had requested x-rays from at the local hospitals.

The placebo group received microwave radiation at the lowest possible setting while the treatment group received traction, mobilization and manipulation (by the Maitland type) and abdominal and spinal exercises. Results at the one month assessment were of borderline significance except that the treatment group did get more people back to light work. However, by three months there were no statistical differences and no trends between the groups and at one year there still were no differences between the groups.

This trial received a letter from the Osteopathic Medical Association stating that you cannot treat patients with only one system of manipulation (16). The author went on to say that even for the same patient he often uses the Oregon or hold system and if this fails, the Hoover for one cannot just rely on the Maitland system alone. This letter serves to illustrate just how complex the manipulation trial would have to be in order to satisfy many of the critics.

There are, of course, critics of manipulative treatments and authors have reported side effects such as increasing pain secondary to manipulation. Perhaps the most serious side effect reported were two

cases of massive posterior sequestration of the lumbar discs resulting in paresis to the patients (46).

Evans conducted a cross-over trial comparing a rotational thrust manipulation with distraction both to the left and to the right (27). Thirty-two patients with chronic low back pain were treated three times at weekly intervals by this manipulation followed by a three week rest period. The second group had the rest period first followed by the manipulation treatment. Codeine was given to both groups. The results stated that patients who had the manipulation first had significantly less pain at the end of the four week period. However, the results are broken down into so many different groups and variations that it is difficult to follow the authors paper. At one point the author did concede that the first week of manipulation treatment was more painful than the corresponding week in the control group. This comment has been noted before in manipulation trials - that the treatment itself is painful.

### 3.16.3 Chiropractic Treatment:

"Ever since 1895, when D.D. Palmer, erstwhile 'the magnetic healer' and founder of the chiropractic movement, claimed to have restored a deaf janitor's hearing by manipulation of the spine, organized medicine has considered chiropractics a form of quackery and campaigned against its acceptance" (88). Chiropractors insist that it is far more than simply a form of physiotherapy for back pain. It

claims to be an alternative system of primary health care - a scientific profession that is at least as competent as medicine in the diagnosis and non-surgical treatment of most human ailments.

There is a scarcity of scientific data on the validity of chiropractic theory and the effectiveness of chiropractic therapy. In fact the first experimental study of the basis for the theory for vertebral manipulation to be published in a recognized journal appears in 1973 (14). However, a group of general practitioners reviewed the results of approximately 122 cases of back pain seen by a chiropractor and 110 cases seen by general physicians in the area of Salt Lake City, U.S.A. (51). Results by two measures of outcome, patients' perception of improvement and patient satisfaction, showed that the chiropractors were as effective with the patients as were the physicians.

The report of the Working Group on Back Pain, chaired by Archie Cochrane, reviewed the chiropractic literature and calls for well designed comparative trials particularly of manipulative treatment which represents chiropractors, osteopaths and acupuncturists (104).

#### 3.16.4 Acupuncture:

The Working Group on Back Pain reviewed the world literature on acupuncture as a treatment for back pain and concluded that it too must participate in rigorous trials in order to assess its effectiveness (104).

Although there is extensive literature on acupuncture in acupuncture journals, it is rarely mentioned as a form of therapy in any medical journal.

Two Canadian studies have been reported using acupuncture in low back pain. The first by Rapson was presented at the OMA Section of Acupuncture and showed the results of 91 patients treated by this method (87). However, the study lacks rigor as there were no controls. The other study also had no controls but like the first one concluded that acupuncture was in fact an effective method for low back pain (25).

#### 3.16.5 Bed Rest:

There have been no randomized clinical trials using bed rest as one of the forms of therapy.

The advice for bed rest is based on empirical evidence that people with low back pain feel better when they are not moving. It has also been established by the same evidence that if you are lifting something heavy when you have back pain, you are likely to feel worse (63). Perhaps a second reason for bed rest is that you can't be lifting very much if you are in bed. Likely the third source for bed rest comes from the treatment of prolapsed lumbar discs (63). For years the surgeons have used this as their main conservative therapy prior to operating on the patient. The general rule here is that if

a patient is not better after two or three weeks of complete bed rest a myelogram and possibly surgical intervention are needed.

Several comments should be made regarding the basis for this use of bed rest. The fact that some patients with low back pain feel better in bed does not necessarily mean that the bed rest will make them better sooner. It is possible that if one could relieve their pain with analgesics and have them somewhat mobile that they would get better faster than a comparable group who were placed in bed. The main concern of physicians that patients might lift something during an episode of back pain and thus advising them to go to bed seems rather extreme and it seems more reasonable to advise a patient not to lift any heavy objects.

Finally, even if bed rest is proven to be important in the treatment of prolapsed discs, it must be tried in a wider range of back conditions.

Some trials have included bed rest, usually with analgesics as a form of control group. Coyer used it as a control group against his manipulation of the lumbar spine (13). There were no differences between the groups at three weeks, and if his six week outcome was evaluated properly, counting his drop-outs, there were no differences between the two therapies at six weeks either. Unfortunately, there is no mention of the length of bed rest nor any evidence that the authors checked as to whether any patient was in fact resting.

A second study included three groups; mobilization exercises, traction and a control group treated with hot packs and rest only (60). Again no definitions or statement about compliance with the control group are presented.

Even, in an otherwise well designed randomized controlled trial, bed rest was not monitored (3).

#### 3.16.6 Exercises:

The most commonly prescribed remedies for patients with low back pain, at least by orthopedic surgeons and physical medicine doctors are various forms of physical exercise. Different flexion and extension exercises have been recommended in order to increase the mobility of the spine and the strength of the abdominal and back muscles. As was mentioned in the basic research section of this thesis, studies have been done looking at the effects of these exercises, and there are a number of control clinical trials using exercise as one of their treatment groups.

Nachemson and Elfstrom have shown that many of these exercises increase the load on the lumbar spine that it often reaches the magnitude as high as those measured in standing and leaning forward with weights in the hands (81, Figure 5)

With regard to disc pressure, isometric exercises seem to be less stressful (82). Two control studies have demonstrated that such exercises, alone or in combination with traction, give better clinical



results than ordinary flexion and extension programmes (60,54).

It remains to be shown that strong muscles protect the back from painful episodes.

In the one trial by Lindstrom, he had three treatment groups (60). One, a control group with hot packs and rest. The second group was what he called conventional therapy consisting of hot packs, massage and a combination of mobilizing and strengthening exercises. The third group contained the isometric exercises but also contained intermittent pelvic traction. In this study it was reported that the traction and isometric exercises were statistically significantly better, but one must be cautious because the numbers in some of the cells were extremely small and in fact in four cells there were zero numbers. However, this study taken with Kendall's study in which he used a double-blind randomized control trial on three forms of exercise, mobilizing exercises, isometric exercises and back strengthening exercises, show the best results were obtained in the isometric exercise group (54). In addition, one of the other interesting results reported was the number of patients made worse by the other two exercises. In the case of the mobilizing exercises two patients out of fourteen reported they were worse after the treatment and five patients out of fourteen on the back extensor exercises reported they were worse after treatment.

No evidence has been presented that subjects with low back pain possess particularly weak muscles, except when they have been kept off work for a long period of time (77). On the other hand it is known that in certain situations, i.e. while lifting and carrying heavy objects, the increase in the intra-abdominal and intrathoracic pressure from contraction of the abdominal and intercostal muscles will help to relieve some of the load on the lumbar spine (75). It should therefore be regarded as rational for patients in their rehabilitation programme after a long period of low back pain to perform isometric abdominal muscle exercises. Also in these patients, special preference should be given to the training of quadriceps muscles, as these take more load when lifting weights the correct way than the wrong way. (Figure V).

Kendall describes his use of lumbar isometric flexion exercises in detail in a paper reported in Physiotherapy (55). He comments on the possible mechanism by which these exercises could work. He states that in a large number of patients suffering from low back pain an accentuated lumbar lordosis with lax abdominal muscles is often noted. Isometric exercise when followed by the patient tends to correct this postural abnormality.

### 3.16.7 Back Education:

A number of authors have called for or included back pain

advice as a treatment for these patients. The underlying point appears to be that one can instruct the patient carefully to avoid certain movements and postures in daily life that were felt to increase the load on the back (17,82). From that point of view straight standing is better than unsupported sitting (82). In sitting, the back should have a good lumbar support and the hip and knee joints should be kept well flexed. Forward bending should be avoided as much as possible and especially for longer periods of time. When lifting weights, great advantage, from a mechanical point of view, is obtained by teaching a patient to avoid flexion of the back. He should be instructed to flex the knees and keep the spine as straight as possible so that when lifting he makes use of the knee extensors. From a clinical point of view, coughing, straining, and jumping, have been known to exaggerate the symptoms of back pain (48,47).

An educational programme similar to that described above was tested in a randomized trial by Berquist-Ullman against a control group of placebo short-wave treatment and another active treatment group, consisting of various forms of physiotherapy (3). The patients in the physiotherapy group had individualized exercises depending on the diagnosis by the physiotherapist. The treatments used by the physiotherapist were stabilization gapping, articulation, stretching, and static and dynamic exercises. The authors concluded that the back school or the physiotherapy were both superior to the placebo treatment

but the back school also reduced the absence from work significantly better than the combined physiotherapy.

### 3.16.8 Pain Relief:

Physicians generally offer pain relief to patients with back pain. There are minor drugs such as aspirin with or without codeine, but an unknown number of certain anti-inflammatory drugs are also dispensed, usually on this continent in the form of Indomethacin. Two trials have been reported using Indomethacin in low back pain. In the first one there was a positive response with most of the patients that had been subdivided into four groups (7). Unfortunately, there were no control groups. In 1974 a double-blind trial was conducted with Indomethacin against Prinalgin (50). The results show that there was no difference at the end of one week between the two drugs.

### 3.16.9 Aggressive or Invasive Treatments:

There are a number of treatments in this area such as chemonucleolysis, acupuncture, percutaneous radiofrequency denervation of the facet joints, steroid injections; all have claimed good or excellent results, however, there have been no randomized clinical trials completed (29,95,99).

### 3.17. SUMMARY OF TREATMENTS

The evidence on most approaches to therapy is unsatisfactory and often conflicting, largely because many forms of therapy have not

been evaluated in an acceptable and scientific manner. It could be successfully argued that the final answer is not in any particular form of treatment. However, it does appear that in the area of muscle exercises in the early form of treatment and certainly in the rehabilitative part that isometric exercises have a place. One well designed study did show that back education in the form of teaching patients how to adjust and work with their backache in their normal daily activities was as equal or better than physiotherapy and was better than the control group.

A few reasonably well designed studies have showed some benefit from various forms of manipulation. However, there is an unsettling trend in some of them in which the patients are often made worse before they are made better, and many different schools have developed making studies very difficult.

Bed rest as a form of treatment has received only superficial attention in any trial and has not been subjected to any randomized control trial.

#### 4. RESEARCH DESIGN (Table XI)

The Question: Does the addition of physiotherapy or bed rest, singly or in combination, to patients receiving analgesics for low back pain improve clinical outcomes?

##### 4.1 INTRODUCTION

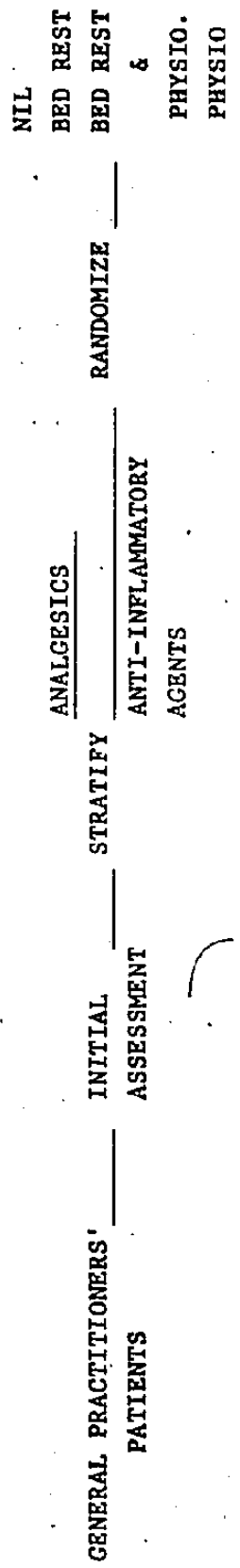
A group of patients suffering from low back pain who present themselves to their local general practitioner will be entered into the randomized clinical trial. This trial will evaluate four groups: physiotherapy-bedrest, physiotherapy alone, bedrest alone and nothing (2 x 2 Factorial Design). All patients will be given pain-relieving medicine; and objective outcomes will be measured (Table XII).

After the patients have passed the inclusion and exclusion criteria they will be stratified according to whether the general practitioner has placed them on regular analgesics or anti-inflammatory agents. They will then have a base-line assessment and be randomized into one of the four groups.

At one and three months, assessment for outcomes will be carried out by an observer who is blind to which treatment group the patients are in. Outcomes will consist of change in patients' report of change in range of motion of the back and in straight leg raising,

TABLE XIII

FLOW OF DIAGRAM OF TRIAL



OUTCOMES

1. Pain relief
2. Normal, daily activities.
3. Return to work.
4. Status of back.
5. Relapse.

TABLE XII

TABLE OF FACTORIAL DESIGN

Bed Rest

		Yes	No
PHYSIOTHERAPY	Yes	Bed rest and	physiotherapy
EDUCATIONAL		physiotherapy	package
PACKAGE	No	Bed rest	NIL

\* each group gets analgesics



return to work or a return to normal daily activities and finally the time of the first recurrence of back pain.

4.2. METHODS OF PROCEDURE (see Table X)

4.2.1 Patient source:

All potential candidates for the study sample will be identified by the general practitioners of five group practices in the City of Hamilton.

4.2.2 Patient selection:

- A) assessment - patients with low back pain will undergo base-line assessment by means of a questionnaire administered by the receptionists and a physical examination done by their own general practitioner.

The questionnaire will assess the following:

- i) normal demographic data on the patient  
(Appendix I)
- ii) characteristics of the pain (Appendix I)
- iii) daily activities questionnaire (Appendix II)

4.3 INCLUSION CRITERIA

Any patient who presents to his or her general practitioner's office with low back pain\* and who has met the following criteria.

- 1) Pain localized to the lumbosacral area, with or without radiation to the thigh.
- 2) Duration of pain before entry to the trial, not longer than four weeks.
- 3) A pain-free interval six months before the onset of the current episode.

4.4 EXCLUSION CRITERIA

- 1) Any patient who has had a treatment that involves the lumbosacral vertebral column in an invasive procedure.
- 2) Spondylolisthesis
- 3) Infections of the vertebral column.
- 4) Tumors, primary or secondary of the lumbosacral vertebral column.

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\* Definition of Low Back Pain: Pain between the twelfth thoracic spine and the last sacral spine. The pain may radiate into one or both buttock areas or to one or both thigh regions. The pain would be of sufficient severity to bring the patient to his or her general practitioner and to be interfering with the patient's normal daily activities. (Normal daily activities are defined by question 2 in Appendix II).

- 5) Ankylosing spondylitis: This disease can be diagnosed when the patient has four out of five of the criteria below (or number six and any other).
- i) low back pain of over three months duration, unrelieved by rest.
  - ii) pain and stiffness in thoracic cage.
  - iii) limited chest expansion.
  - iv) limited motion in the lumbar spine.
  - v) past or present evidence of iritis.
  - vi) bilateral radiographic sacroiliitis.
  - vii) radiographic syndesmophytosis.
- 6) Fractures of the vertebral column.
- 7) Patient has objective evidence of a prolapsed disc. (Any one or more objective neurological signs which would be compatible with a patient's history).
- 8) Any concurrent diseases which is active in the opinion of the patient's general practitioner, and likely to affect the patient during the trial.
- 9) Paget's disease.
- 10) Pregnancy.
- 11) All patients will have the following blood tests: ESR, Serum calcium and phosphorus, acid and alkaline phosphatase. These tests have been found to be highly

reliable in diagnosing neoplasms in patients with low back pain. An x-ray of the lumbosacral region will also be ordered on each patient (A-P and lateral views). If any one of these blood tests are positive the patient will be excluded from the study. Patients will be excluded from the study if the x-ray shows any of the exclusion conditions.

- These exclusion factors will not have a large effect on the sample size as they make up less than 4% of the types of back pain seen by general practitioners.

#### 4.5 ETHICAL CONSIDERATIONS

Those patients who fail to meet the inclusion criteria will be excluded from the trial but still will be offered treatment. Those who do meet the admission criteria will be informed of the full nature of the trial, any attendant risks that might be involved, and what would be expected of them if they chose to participate. The individuals involved in the study would have the right to withdraw from the study at any time without loss of care. They would remain free from assault and would be guaranteed confidentiality. Should the therapist treating the patient involved in the study decide at any time that the treatment is increasing the patient's symptoms the treatment will be discontinued and counted as a failure.

Eligible patients will be asked to sign a consent form (Appendix III). This consent form will outline the conditions of the trial and guarantee that the patient may quit the trial at any point without jeopardizing their future care.

#### 4.6 STRATIFICATION

Stratification prior to randomization in the trial would be important if one or more factors in the population other than the factor being examined in the trial could influence the outcome. Having reviewed the literature there do not appear to be any factors that fall into this category. Bergquist-Ullman (3) did give a reasonable historical explanation for stratifying patients on occupation and psychological traits. However the results of their trial when analyzed failed to show that occupation and psychological traits were major confounding factors.

The trial being designed deals with the largest single group of back pain sufferers, but has excluded ones known to have serious disease, such as cancer or prolapsed disc. Therefore, there is no need to stratify for those diseases. (See Exclusion Criteria)

Randomization, in itself, is a method of insuring comparability of groups should there be factors which are unknown to us at the present time.

The patients will likely all be offered some form of pain relief and/or anti-inflammatory drugs. This is going to be continued as this is the common treatment in general practice at the present time. Although there is no hard evidence that anti-inflammatory agents are more powerful than normal analgesics in the treatment of this type of patient in this trial, it is felt for clinical credibility that the patient should be stratified into the simple analgesic group or anti-inflammatory group.\*

4.7 DESCRIPTION OF THE THERAPEUTIC MANOEUVRE

Five groups of general practitioners will be sought to participate in this trial. A group of general practitioners will be defined as two or more physicians working in the same office.

Any patient presenting to his own family physician with the sole complaint of back pain meets the exclusion and inclusion criteria and will be admitted to the trial. History and physical examination will be performed on the patient by the patient's own family physician.

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\* Description of Anti-Inflammatory Drugs - A drug which has a higher potency than aspirin. e.g. phenylbutazone, Indomethacine or Codeine. Minor drugs include simple analgesics such as aspirin.

Because the presence of a second disease may markedly affect the ability of patients to participate or be assessed in this trial, only patients who currently only have one active disease, namely low back pain, will be admitted to the trial. If the patient has a chronic disease which is under good clinical control and in the opinion of the family physician is unlikely to change in the next four weeks, the patient will be accepted into the trial.

The history will not be standardized as the important data needed from the history will be obtained through the questionnaire described below.

Physical examination will also be left to the discretion of the physician with the exception of two areas. A) Range of motion of the back in flexion, B) straight leg raising.

One receptionist in each group who has previously been tested for ability to administer the McGill pain questionnaire will administer this and a modified health index questionnaire (modified from Chamber's) to each patient (8,68).

The receptionist will then dial a central number which will serve as a center for random assignments to one of the four treatment groups. The patient will either receive a physiotherapy educational package, or a physiotherapy education package plus bed rest, bed rest alone, or none of the treatments.

The physiotherapy will consist of administration of isometric exercises by a physiotherapist (Appendix IV,V). Each of the five groups will be visited by the same physiotherapist two half days in the week in order to be available for the patients in the study. The patients in Group One will receive training three times during a ten day period, each period taking approximately 10 minutes. Although the physiotherapist will spend three visits teaching the exercises, it is expected the patient will continue these exercises at home. Instructions will be that the patient is to repeat these exercises 12 times, 3 times a day, and to repeat standing in a position as often as possible during the day. Included in this time is a 5 minute slide tape show illustrating proper back care prevention program. Details of the type of isometric exercises and the educational package are available in the appendices (IV and V).

Group two will receive the above physiotherapy educational package but will be instructed to have bed rest until pain-free or for 10 days (whichever comes first).

Bed rest will be defined as lying in bed in any position other than the prone position. The patient will only be allowed out of bed for bathroom privileges, meals or to come to the office for the physiotherapy-educational program.



All patients will be allowed to take medication as prescribed by their general practitioner. However, general practitioners must decide after history and physical whether the patient is on a "major" or "minor" drug so that they can be properly stratified prior to being randomized by the methods center.

The trial will attempt to mimic the normal general practitioner's treatment pattern so as to obtain maximum compliance from the doctors. With this in mind, each patient will be given a recheck appointment by his or her own general practitioner at day 14.

At day 28, each patient will be given a final appointment. However, at this time they will be assessed historically and physically using the same method as the initial assessment by another general practitioner in the group who is blind to which treatment group the patient was in.

At this point the receptionist also has the patient complete the McGill pain questionnaire and the modified health index questionnaire.

#### 4.8 COMPLIANCE

Compliance with the physiotherapy-educational package will be defined as showing up for the appointment with the physiotherapist.

There are two areas of concern in the measurement of compliance in this trial, the first being compliance with bed rest and the second

being some measure of compliance with the physicians' medication prescriptions.

#### 4.8.1 Medication Compliance:

A reliable and valid method of pill-counts has been developed by the Department of Clinical Epidemiology and Biostatistics at McMaster (92,93). This form will be used in order to do pill count assessments by the general practitioners' nurse:

For all groups a pill count will be done at the 28 day visit when the patient comes to the doctor's office. The patient will be asked to bring his/her medication bottles to the office on this occasion. It is appreciated that a bias may enter into this pill count as patients will realize that their medication will be checked at the office. It is felt that pill counts at the patient's home, in this particular study, would not be economically feasible. Patients who do not bring in their medication will be counted as non-compliers.

#### 4.8.2 Bed Rest Compliance:

This, of course, is very difficult to measure in this trial because there is no known conveniently reliable and valid method. Several methods will be described in the hope that the combination will give some idea as to how many people complied with that treatment instruction.

A) Self-reporting: the patients will be asked to complete a short form at their 28 day assessment in an attempt to get their compliance rate.

B) Relative or Family Member Reporting: using the consent form of the health index questionnaire, a consent form will be obtained in order to phone a relative or family member ostensibly to get an independent assessment of the patient's illness (8). This telephone call could be used in order to get some idea of how well the patient is also complying with the bed rest.

C) Recently a device called a Large-Scale Integrated Motor Activity Monitor was developed to examine physical activity (57). This unit, which is slightly larger than a wristwatch, records body motion at various body locations. One of the interesting features of this machine is that the patient cannot see the reading and activation is by placing a magnet near the side of the unit at which time a visual light emitting diode, with a four decimal digital display is then activated. Reports are available on the interunit reliability which is extremely high (57). The issue of whether the devices are accurate reflection of movement was examined by Foster, and he found correlations between .92 and .98 tested against tread mill activity (33). Laporte reports other data on the device. He found that units do not appear to interfere with normal behaviour; and that the units are extremely durable in active populations. He reports a statistically significant difference

in the variability of activity of university students. Here the device was able to pick up differences in activity in a group of men who superficially might have been thought to have had identical activities.

In a second population study, the analysis between a physical education group and a non-physical education group showed that there was a statistically significant difference in their activities. They were also able to show a significant correlation between the per trunk activity and the rate of energy expenditure per hour ( $r = +.69$ ,  $P = <.01$ ).

These units cost \$200.00 each. The sample size needed in this trial is 260 patients, and this fact makes this apparatus too expensive as a measure of compliance. However, 16 units will be used to validate the patient's history of activity. Four units will be randomly assigned to 4 patients in each treatment group. Every 6 days (the life of the battery) for the first month the monitors will be rotated to 16 different patients. Thus a total of 64 patients which will be used in this validation procedure (25% of the sample size).

D) Home Visit: a home visit by a research assistant is planned for more than one purpose. The purpose relevant here though is that she would be able to report on a measure of bed rest compliance at least on the day that she visits the home.

4.9 CO-INTERVENTION

All patients will receive the same screening blood tests and diagnostic radiology. The main concern for co-intervention in this trial is that the physiotherapist's personality and exposure to the patient present in only two of the four treatment groups. In other words, it is possible even with an ineffective physiotherapy program, that the physiotherapist's "tender loving care" might alter the outcomes for the patients that had this treatment. In order to try to minimize this attention placebo, the research assistant will be sent on a home visit to the two other groups.

The research assistant's instructions will be to spend approximately 20 minutes in the home with the patients on bed rest alone - the main thrust of the visit is to be a social visit and that they are only in the vaguest terms to respond to any kind of medical management. In the case of the patients who are getting a combination of physiotherapy and bed rest treatment, the home visit will be very brief as its real purpose here is to get a measure of best rest compliance but not to increase ~~the~~ attention bias to the patients.

It does appear, however, that the patients who are getting the physio-educational package will likely have more attention time from a health professional but the home visits will certainly minimize this effect.

4.10 CONTAMINATION

This refers to the inadvertent administration of the same or related therapeutic programmes as those which our trial participants are receiving. Contamination is not thought to be likely in this trial. This is because the majority of patients who have come to their own general practitioner for treatment would probably stick by that treatment for at least the trial period of one month without becoming unduly depressed with poor results.

Nevertheless, there are other routes for patients such as chiropractors, osteopaths, changing family doctors, or going to an emergency room.

Changing family doctors during the one month is unlikely and can be monitored by release of records information and can be followed quite easily from "no shows" at any of the assessment times which will be charged to the original group.

Emergency room visits in the city can be traced as the family physician receives a copy of all emergency room visits by his own patients.

The osteopath problem is solved in that there are no osteopaths listed in the yellow pages in Hamilton. There are, of course, a number of chiropractors available. Patients, at their 28 week assessment, will be asked whether they had seen any chiropractors as a form of self-reporting. Patients will report other treatments. In a

California walk-in clinic for back pain, a considerable number (20%) reported seeking help elsewhere (38). In the current trial it is felt that co-intervention will not be that high as the patients will be seeing their own personal physician.

It is unlikely that chiropractors would release information on patient visits to a physician even if they were questioned.

#### 4.11 DIAGNOSTIC CRITERIA

Outcomes in this trial will be measured by five different parameters.

1. Assessment of pain (Appendix I)
2. Change in daily activity level (Appendix II)
3. Change in back flexion and straight leg raising (Figure VI).
4. Patient reports as to: a) return to normal daily activities, b) return to work.

#### 4.12 PAIN - RELIABLE AND VALID MEASURES (Appendix I)

Numerous approaches to the measurement of pain range from the simple analogue scale to a questionnaire approach through to a computerized system for assessment of pain (with an algorithm to describe the interaction of the components of pain) (49,68,22). What all these methods have in common is an attempt to assess clinical pain by a reliable, valid and sensitive index. These methods of measuring

pain are not to be confused with methods of measuring experimental pain. It is easier to study experimental pain because it can be measured in terms of intensity of the stimulus. In clinical pain the nature of the stimulus is often unknown, its intensity is often difficult to measure, and the severity of the disease is not clearly related to pain because pain is modified by such factors as individual patient pain threshold.

In 1965, Melzack reported a new theory for pain mechanisms which has subsequently become known as the gate-control theory of pain (70). By 1975 he had developed a tool for measuring clinical pain (McGill Pain Questionnaire) (68). This questionnaire consists primarily of three major classes of word descriptors - sensory, affective and evaluative - which are used by patients to specify subjective pain experience. It also contains an intensity scale and other evidence to determine the properties of the pain experience. The questionnaire is designed to provide quantitative measures of clinical pain that can be treated statistically.

Four types of data can be obtained from the questionnaire:

a) A pain rating index consisting of the sum total of the scales values chosen PRI(S), b) the PRI(R) index which gives the rank values of the words, c) the number of words chosen (NWC), and the present pain intensity (PPI), which is measured by the number-word combination.

Correlations between PRI scale and PRI rank are higher than 0.9 for all categories. Correlations of 0.89 and 0.97 are reported between



NWC and PRI(S) or PRI(R). Finally, the PPI correlates significantly ( $P < 0.01$  in all cases) with the total number of words chosen and the PRI for all categories. The PPI appears to be more liable than the other indices and more susceptible to other issues such as the patient's mood and past pain experience.

Using an experimental pain stimulus in a group of volunteers, Melzack was able to show very high correlations between the anchor scales subjects choose and the changes and the pain stimulus ( $P < 0.001$ ).

Taken together, all correlations are highly significant statistically and indicate an internal consistency among different categories of the PRI and among the three indices in the questionnaire. It is apparent then that the questionnaire provides valid indices for some dimensions of pain.

Correlation coefficients between rank (R) and scale (S) values for his subclasses were determined for several pain syndromes. In the case of back pain all values were above 0.82.

The questionnaire has been used to determine the effectiveness of alpha-feedback training, hypnotic training in several clinical pain syndromes. Here the PRI(R) was found to be the more valid index of change in pain.

Melzack and Torgerson in a subsequent study were able to show a high degree of agreement on the intensity relationship among pain

descriptors by subjects with different cultural, socioeconomic and educational backgrounds (72).

The questionnaire was administered to 95 patients for whom a diagnosis had been carefully established for eight diseases (including degenerative disc). In a multiple group discriminant analysis of the results, each type of pain was found to occupy a different region in the multidimensional space derived from the pain descriptors. Further statistical analysis of the data revealed that the differences among the constellations of works for the eight syndromes are statistically significant. A computer using descriptor set for each patient was able to correctly classify 77% of the cases (71).

In a cohort analytic trial designed to assess the Brompton mixture effects on pain in cancer, the questionnaire provided an objective measure of pain and high correlations between PPI and PRI scores (69). The questionnaire was able to gauge the magnitude of the effects of the mixture, its relative effects in different environments and how the Brompton mixture compares with traditional methods of pain control in cancer patients.

The test is also easy to administer; it takes about 15 minutes of the patient's time, although some supervision is needed. The final reason this form is used to measure pain relief in the present study is that the questionnaire is widely used throughout the world as one of the best measures of relief of pain.

A problem occurs at the time of final assessment at 28 days when some patients may still be taking analgesics and others may not. This will be handled by strict rationing of the total amount of medication given to patients so that they will in fact not have any medication left at day 26 through to day 28. In addition the patients will be asked not to take analgesics 48 hours prior to their final assessment time.

The McGill system also has a home recording card which contains one subsection of the overall questionnaire and asks the patient to record pain levels at home (68). The suggested completion rate is four times a day for whatever period is necessary.

It is unlikely that patients would comply with the four times a day regime for four weeks and so everyone from each treatment group will be asked to do this in their final week.

#### 4.13 HEALTH INDEX QUESTIONNAIRE (Appendix I)

Low back pain frequently leads to problems in normal daily activities. One of the expected benefits of a therapy for low back pain would be the patient's ability to return to normal physical functioning. In 1977, a multidisciplinary group at McMaster published the results of a health index questionnaire which was designed to measure physical function in free-living populations (8). In the development of the questionnaire, the authors tried to meet seven

prerequisites: comprehensiveness, positive-orientation, general applicability, sensitivity, simplicity, acceptability and cost, precision, and amenability to index construction.

The paper reports on the initial health index study where 296 individuals were randomly selected from a seasoned general practitioner's practice. Three general strategies for validation were looked at during the study: face validity, biological validity and clinical validity. The authors concluded that initial evaluations of the resulting health indices suggested that they were biologically and clinically valid (11). They further stated that these indices had been successfully applied in a randomized trial involving nurse practitioners and family physicians in the delivery of primary health care (10).

In a study of 65 ambulatory out-patients in a rehabilitative center, patient responses to the physical function items predicted well the assessments of an occupational therapist and psychiatrist. Retest reliability between administration of the physical function questions was 0.80 (32).

This multidisciplinary team has continued in their efforts to achieve new dimensions of validation, and Chambers reports that the initial evaluation of the resulting health indices suggest that they concur with separate health assessments by the subject and the health assessments of a clinician (09).

This health care index will be used in this randomized clinical trial of therapeutic manoeuvres as a method measuring outcomes. In this study the total questionnaire will not be used, but only the section used to assess physical function. The only modification that is necessary for this trial is the addition of one question assessing patients' physical difficulty sitting in a chair.

Also, incorporated into this questionnaire will be a question allowing the research assistant to contact a person who is familiar with the patient's everyday health which is a relative or friend. With this approval, a research assistant will be able to obtain another check on compliance with bed rest.

The questionnaire will be completed by the patient at the initial visit and four weeks later.

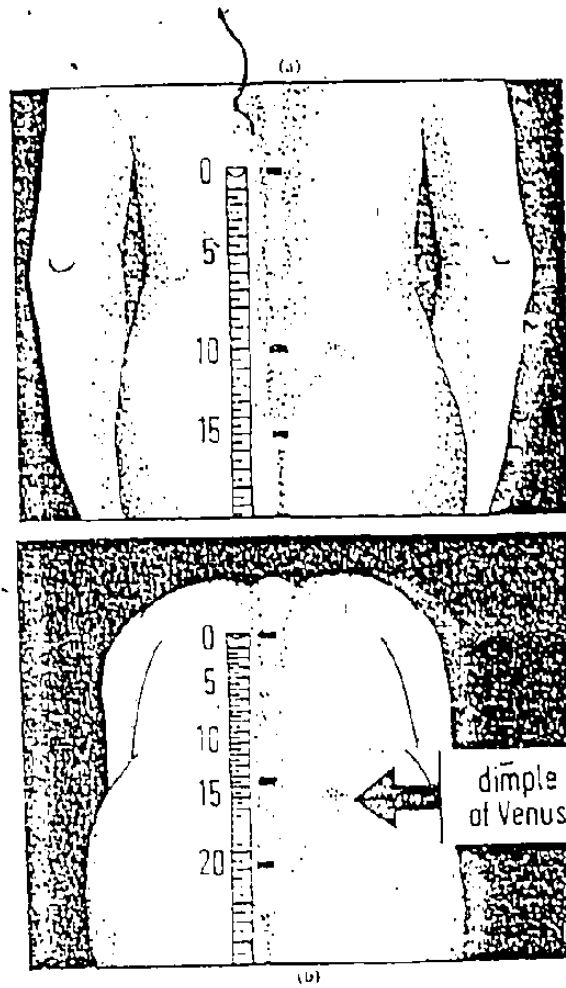
#### 4.14 PHYSICAL ASSESSMENT (Figure VI)

The general practitioners doing the initial and post-treatment assessment will be allowed to do their own history and physical assessment. Important factors in history are already being picked up by the standardized McGill pain questionnaire and only two points in physical exam will need to be standardized in terms of showing reliability and validity measurements.

In a randomized control trial by Berquist-Ullman, range of motion of the lumbar spine were assessed by a reliable and valid method

FIGURE VI

Measurement of Lumbar Flexion



Measurement of anterior spinal flexion by a modification of Schober's method (Macrae and Wright, 1969).

pioneered by Schober and modified by Moll and Wright (3,74). However, the trial showed that only spinal flexion could separate patients with clinically significant group from others. Therefore, only spinal flexion will be measured objectively using methods developed by Moll and Wright (Figure VI). Flexion is measured by plotting marks on the following locations of the patient's back: 1) the lumbar sacral junction, (the spinal intersection of the line joining the dimples of Venus), 2) 10 cm. above and 5 cm. below the lumbosacral junction.

The distance between upper and lower marks is measured while the patient is standing erect and then in maximum flexion. The difference between the distances represents the ability to flex the spine.

Prior to the study, general practitioners will be tested on the use of this measurement technique to make sure that the measurements are reliable. Each physician will be tested against an orthopedic specialist's measurements. The general physician's measurement must be within 1 cm. of the orthopedic's measurement in 16 out of 20 patients.

The second objective measure will be straight leg raising (SLR). Charnley in 1951 and Grieve in 1970 reported on the validity of this test in assessing severity of nerve root irritation in case of low back pain (12,39). The test is now used universally as the standard

for nerve root irritation. Most major trends reviewed used this measurement as an index of severity or as an outcome measure.

In practice, physicians merely estimate the degree of SLR and so reliability could be a problem. Physiotherapists have used a simple reliable measuring instrument, a goniometer, to accurately assess the number of degrees of SLR at first pain. This device will be pre-tested with the general practitioners in the same manner as the flexion test.

#### 4.15 RELAPSE RATE

From the pain questionnaire the number of days between recovery from the initial episode and the first recurrence of pain will be used to measure time to relapse. Date of relapse will be assessed by two methods: a) medical records will be reviewed by the research assistant for a minimum of three months past the final assessment date, b) the research assistant will phone each patient every month for three months after the final assessment for recurrence of pain.

#### 4.16 SAMPLE SIZE (Table XIII)

Seventy percent of these patients are expected to be better at one month. In my opinion, the treatments under study could only be judged valuable if they increased the proportion of recovered patients at one month to 85%.



TABLE XIII

Sample Size

Physiotherapy-  
Educational  
Programme

	Bed +	Rest -	
+	65	65	130
-	65	65	130
	130	130	260

Using an Alpha of .05 and a Beta of .10 in a one-tailed test, a total sample of 260 is needed; 65 in each of the 4 treatment groups (Table XIII).

#### 4.17 FEASIBILITY OF THE SAMPLE SIZE

In order to obtain an accurate assessment of how many new cases of low back pain are presented to general practitioners in the city, four groups were asked to document their low back pain cases for a period of 2-4 weeks. It appears that a general practitioner will see about 15 cases per month of low back pain, three of these cases will likely be excluded by the criteria used in this trial. It is estimated that a further two cases would refuse to participate in the trial leaving 10 cases per month as an expected number per physician. Using five groups of physicians the trial would therefore require an intake period of six months (300 cases) in order to obtain the desired sample size. Given a three month following on each patient it should thus be possible to complete this study in one year.

#### 4.18 ANALYSIS

Of the four outcomes three (changes in flexion, change in pain, average number of days necessary for return to work or to normal daily activities) are measured as continuous variables. For each of these measures the main effects of bed rest and the educational-physiotherapy package, and also the interaction between these treatments will be assessed using analysis of variance.

Interactions between the treatment physiotherapy and bed rest will be assessed using analysis of variance. If the physiotherapy by bed rest group in the analysis of variance shows a non-significant "F" value, then one can conclude that the therapies have neither synergistic nor an antagonistic effect on each other. If, on the other hand, there is a statistically significant "F" value for the combined group, then the mean values, for example, for pain, would have to be examined to see whether there was a synergistic or antagonistic interaction.

A chi-square test will be used to compare patient reports of a relapse (recurrence of pain sufficient to cause them to seek professional help) within three months after their recovery from the initial episode.

A life table analysis (log rank chi-square) will also be performed to compare the treatment groups on time to: a) recovery from the initial episode ; b) return to work or daily activities and c) time from recovery of the initial episode to a relapse.

The daily activities questionnaire consists of categorical data. Patients' responses to the questionnaire will be categorized by judges who are unaware of which treatment group the patient is in. The judges will be asked to place each patient's response into one of three categories (mild, moderate, severe) of back problems. These findings can then be analyzed by a chi-square analysis.

4.19 DETAILED BUDGET

Expenditures are requested for one fiscal year. The estimated study time is approximately 12 months. The first six months will be the enrolment time for the patients with the last follow up being completed at approximately nine months. The remaining months will be for data analysis and for preparation of reports.

4.19.1 BUDGET

A) SALARIES	% OF TIME	NO. OF MONTHS	TOTAL
(1) Research Assistant/ secretary \$1083./month Fringe benefits (15%)	Full	12	\$12,996.00 1,949.40
(2) Physiotherapist (Step 1) \$16,000. Fringe benefits (15%)	Full	6	8,000.00 1,200.00
(3) Receptionist fee \$1.00/patient			520.00
(4) Nurse fee: pill count			520.00
B) <u>EQUIPMENT</u>			
(1) Slide-tape playback \$400/each. Five Kodak Model 200			2,000.00
(2) Typewriter, rental IBM \$12/month (8 months)			96.00
(3) Telephone \$12/month			144.00
(4) Motor activity monitor (16)			3,200.00
C) <u>MATERIAL, SUPPLIES &amp; SERVICES</u>			
(1) Stationery, office supplies			750.00
(2) Miscellaneous, stamps, xeroxing			300.00

D) COMPUTATIONAL SERVICES /

(1) Key punching	500.00
(2) Computation	500.00
(3) Statistical consultant \$30/hour for 30 hours.	900.00

E) TRAVEL FOR PHYSIOTHERAPIST

(1) 19.3 cents/mile, 30 miles/week	150.00
(2) Parking \$4.00/week	<u>112.00</u>

TOTAL BUDGET . . . . . \$33,837.40

4.19.2 Budget Justification:

The Research Assistant/Secretary will act as the overall coordinator of the research project. Specific functions will include the randomization of patients, pre-test, and home visits. The Research Assistant that is hired will have a nursing background in order to make her home visiting portion realistic to the patient. It is expected that the Department of Family Medicine will provide the necessary facilities rent-free.

The physiotherapist will be a recent graduate as she does not need sophisticated physiotherapy skills for this particular research project. It is assumed that she also will get a rent-free office for the six month period in the trial.

Receptionists will be given \$1.00 per patient for the supervision of the four questionnaires (two initially and two at completion). It is only the pain questionnaire which needs supervision.

Costs will be involved in the printing of the questionnaires and for coding and keypunching and varifying the results for subsequent computer analysis. The latter would include the writing of a short program and computer time.

Travel has been estimated by assuming that the five physicians' offices are on an average three miles one-way from the home base.

APPENDIX I

McGILL PAIN ASSESSMENT QUESTIONNAIRE

Date \_\_\_\_\_ Administrator \_\_\_\_\_  
Patient's Name: \_\_\_\_\_ ID: \_\_\_\_\_ Age: \_\_\_\_\_  
Address: \_\_\_\_\_ Phone: \_\_\_\_\_  
Referring Doctor: \_\_\_\_\_ Yrs. in Pain: \_\_\_\_\_  
Diagnosis: Low Back Pain

Comments:

Present Drug Intake:

Medication	Dose	Frequency	Duration of relief	Amount of relief	Date Started

Comments, Side Effects:

© R. Melzack, 1974.

Medical History:

A) Date Pain Began: \_\_\_\_\_

B) Circumstances of Onset:

Accident at Work	Following Illness
Accident at Home	Following Surgery
Other Accident	Pain "Just Began"
Comments:	

C) Previous Surgery:

Date	Details

D) Previous Major Illnesses:

Date	Details



Medical History (continued)

E) Previous Physiotherapy/Other Treatments

Date	Details

F) Doctors and Other Health Professionals Consulted Since Pain Began:

Gen. Practitioner	Radiologist
Internist	Surgeon (Gen.)
Neurologist	Psychologist
Obst/Gyn.	Hypnotist
Orthopedist	Osteopath
Plastic Surgeon	Chiropractor
Proctologist	Acupuncturist
Psychiatrist	Clergyman
	Faith Healer
Other/Comments:	

Medical History (continued)

G) Present Programme (s) of Treatment (other than drugs):

<u>Psychotherapy</u> <u>Counselling</u>	
<u>Physiotherapy</u> <u>Occup. Therapy</u>	
<u>Surgery</u>	
<u>Other</u>	

Personal History:

A) Ethnic Group:

B) Marital Status:

Unmarried	Number of Children
Married	No. of Children at home
Divorced/separated	Ages of Children at home
Widow/widower	No. of others at home
Comments:	

Present Pain Pattern:

A) Throughout the Day:

Time	Duration	Time-Pattern
Morning		
Afternoon		
Evening		
Night		

B) Body Position: What happens to pain when:

Sitting	
Standing	
Lying	

C) Has your mood (outlook on life, attitudes to other people, etc.) changed since your pain began? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes: how?

--

Present Pain Pattern (continued)

D) Accompanying Symptoms

	Nausea	Constipation
	Headache	Diarrhea
	Dizziness	Menses
	Urination	Other
Comments:		

E) Other Present Illness:

--

F) Causes of Increase (+) or Decrease (-) of Pain:

Indicate a "+" or a "-" opposite appropriate cause	
Liquor	Sleep, Rest
Stimulants (coffee etc.)	Lying down
Eating	Distraction (T.V., etc.)
Heat	Urination, Defecation
Cold	Tension
Damp	Bright lights
Weather changes	Loud noises
Massage, Vibrator	Going to work
Pressure	Intercourse
No movement	Mild exercise
Movement	Fatigue
Comments:	

Present Pain Pattern (continued)

G) Have you learned ways to relax at moments of tension?  
Yes \_\_\_\_\_ No \_\_\_\_\_

\_\_\_\_\_  
If yes: what methods do you use?  
\_\_\_\_\_

Pain and Sleep:

	always	sometimes	never
Trouble falling asleep			
Medication needed to fall asleep			
Awakened by Pain			
Comments:	Average No. Hours Sleep		

Pain and Sexual Relations:

	Desire	Ability
Same as before		
Somewhat less than before		
Very much less than before		
None at all		
Comments:		

Pain and work/Activity:

- A) Type of Work (incl. housewife): \_\_\_\_\_
- B) Compensation: Yes: \_\_\_\_\_ No: \_\_\_\_\_
- C) Ability to work at regular job: \_\_\_\_\_
- D) Occasional need to stop all activities because of pain: Yes: \_\_\_\_\_ No: \_\_\_\_\_
- E) If "Yes" to D). Number of times: Daily: \_\_\_\_\_ Weekly: \_\_\_\_\_
- F) Comments: \_\_\_\_\_

Eating Habits:

- A) Has your food intake changed since the onset of pain? \_\_\_\_\_  
Details: \_\_\_\_\_
- B) Do you follow a specific diet? \_\_\_\_\_  
Details: \_\_\_\_\_

Pain Description:

- A) Choose one work group

\_\_\_\_\_ Continuous, Steady, Constant  
\_\_\_\_\_ Rhythmic, Periodic, Intermittant  
\_\_\_\_\_ Brief, Momentary, Transient

The following words represent pain of increasing intensity:

1	2	3	4	5
Mild	Discomforting	Distressing	Horrible	Excruciating

- B) Choose the number of the word which best describes:

_____	Your pain right now
_____	Your pain at its worst
_____	Your pain at its least
_____	The worst toothache you ever had
_____	The worst headache you ever had
_____	The worst stomach-ache you ever had

What Does Your Pain Feel Like?

Some of the words I will read to you describe your present pain. Tell me which words best describe it. Leave out any word-group that is not available. Use only a single word in each appropriate group--the one that applies best.

- 1  
1 Flickering  
2 Quivering  
3 Pulsing  
4 Throbbing  
5 Beating  
6 Pounding

- 2  
1 Jumping  
2 Flashing  
3 Shooting

- 3  
1 Pricking  
2 Boring  
3 Drilling  
4 Stabbing  
5 Lancing

- 4  
1 Sharp  
2 Cutting  
3 Lacerating

- 5  
1 Pinching  
2 Pressing  
3 Gnawing  
4 Cramping

- 6  
1 Tugging  
2 Pulling  
3 Wrenching

- 7  
1 Hot  
2 Burning  
3 Scalding  
4 Searing

- 8  
1 Tingling  
2 Itchy  
3 Smarting  
4 Stinging

- 9  
1 Dull  
2 Sore  
3 Hurting  
4 Aching  
5 Heavy

- 10  
1 Tender  
2 Taut  
3 Rasping  
4 Splitting

- 11  
1 Tiring  
2 Exhausting

- 12  
1 Sickening  
2 Suffocating

- 13  
1 Fearful  
2 Frightful  
3 Terrifying

- 14  
1 Punishing  
2 Gruelling  
3 Cruel  
4 Vicious  
5 Killing

- 15  
1 Wretched  
2 Blinding

- 16  
1 Annoying  
2 Troublesome  
3 Miserable  
4 Intense  
5 Unbearable

- 17  
1 Spreading  
2 Radiating  
3 Penetrating  
4 Piercing

- 18  
1 Tight  
2 Numb  
3 Drawing  
4 Squeezing  
5 Tearing

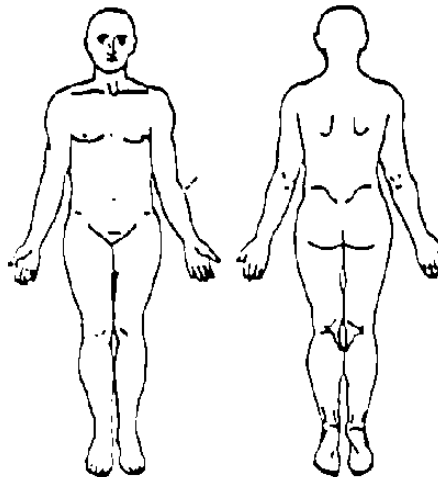
- 19  
1 Cool  
2 Cold  
3 Freezing

- 20  
1 Nagging  
2 Nauseating  
3 Agonizing  
4 Dreadful  
5 Torturing

Where is your Pain?

Please mark, on the drawings below, the areas where you feel pain. Put E if external; or I if internal, near the areas which you mark. Put EI if both external and internal.

ALSO: if you have one or more areas which can trigger your pain when pressure is applied to them, mark each with an x.



Comments:

McGill Home Recording Card

Name: \_\_\_\_\_ Date Started: \_\_\_\_\_

	Morning	Noon	Dinner	Bedtime
M				
TU				
W				
TH				
F				
SA				
SU				

PLEASE RECORD

1. Pain Intensity #: 0 - no pain  
1 - mild  
2 - discomforting  
3 - distressing  
4 - horrible  
5 - excruciating
2. No. of Analgesics you have taken.
3. Please make note of any unusual symptoms, pains or activities on back of card.
4. Record hours slept in morning column.



APPENDIX II

McMASTER HEALTH INDEX QUESTIONNAIRE

SELF-ADMINISTERED FORM

Directions: Please answer each question by circling the appropriate number. Because we want your answers and opinions, we urge you not to talk about your answers or show your completed questionnaire to anyone.

APPENDIX II

McMASTER HEALTH INDEX QUESTIONNAIRE

SECTION A: The questions in the first section ask about your health and whether you are able to do certain things.

1. Today, are you physically able to run a short distance, say 300 feet, if you are in a hurry? (This is about the length of a football field or soccer pitch).
  - 1 NO
  - 2 YES
  
2. Today, do you (or would you) have any physical difficulty at all with:
  - a. walking, as far as a mile?
    - 1 NO DIFFICULTY
    - 2 DIFFICULTY
  
  - b. climbing up 2 flights of stairs?
    - 1 NO DIFFICULTY
    - 2 DIFFICULTY
  
  - c. standing up from, and/or sitting down in a chair?
    - 1 NO DIFFICULTY
    - 2 DIFFICULTY

d. feeding yourself?

1. NO DIFFICULTY
2. DIFFICULTY

e. undressing?

1. NO DIFFICULTY
2. DIFFICULTY

f. washing (face and hands), shaving (men) and/or combing hair?

1. NO DIFFICULTY
2. DIFFICULTY

g. shopping?

1. NO DIFFICULTY
2. DIFFICULTY

h. cooking?

1. NO DIFFICULTY
2. DIFFICULTY

i. dusting

1. NO DIFFICULTY
2. DIFFICULTY

j. cleaning floors?

1. NO DIFFICULTY
2. DIFFICULTY



3. Today, are you physically able to take part in any sports PF  
(hockey, swimming, bowling, golf, and so forth) or exercises  
regularly?

1 NO

2 YES

4. At present, are you physically able to walk out-of-doors PF  
by yourself when the weather is good?

1 NO \_\_\_\_\_

\_\_\_\_\_ 2 YES

a. What is the farthest  
you can walk by  
yourself:

1. ONE MILE OR MORE

2. LESS THAN 1 MILE BUT  
MORE THAN 30 FEET

(ABOUT THE SIDE OF A HOUSE)

3. LESS THAN 30 FEET

b. Are you able to walk  
by yourself:

4. BETWEEN ROOM

5. ONLY WITHIN A ROOM

6. CANT' WALK AT ALL

5. Today, do you (or would you) have any physical difficulty at PF  
all travelling by bus whenever necessary?

1 NO

2 YES

6. Today, do you have any physical difficulty at all travelling PF  
by car whenever necessary?

1 NO

2 YES

7. Do you have any physical difficulty at all driving a car PF  
by yourself?

1 NO

2 YES

a. Is this because of a physical  
'disability?

1 NO

2 YES

8. Today, do you have any physical difficulty sitting in a  
chair for more than 10 minutes?

1 NO

2 YES

9. As part of this research project, we would like to contact one  
person who is close to you and would be familiar with your  
everyday health (such as a relative or close friend).

May we have your permission to hold a short telephone interview  
with the person you select, to ask about his/her impression of  
your health?

1 NO

2 YES Name of this person: \_\_\_\_\_

(please print)

Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Relationship to you: \_\_\_\_\_

THANK YOU VERY MUCH FOR YOUR HELP IN THIS STUDY.

APPENDIX III

PATIENT CONSENT FORM

It has been explained to me by my family physician \_\_\_\_\_ that a study is being done to test the effectiveness of four carefully supervised programs for the treatment of low back pain. All patients will be offered a variety of medications at the discretion of their family physician. For three of the programs patients will be given additional therapies. The first therapy consists of bed rest and a form of physiotherapy. The second receive bed rest.

In order to assess the effectiveness of each program, a choice between them will be made randomly (similar to the toss of a coin). I will complete two questionnaires at the beginning of the treatment, and another two at the end of the treatment. These questionnaires will include questions about my pain and my routine daily activities.

I agree to participate in this study, and understand that I am free to withdraw at any time without compromising my regular treatment

program. The study has been explained to me to my satisfaction, and understanding them fully, I hereby give my consent to enter this treatment program.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

Witness: \_\_\_\_\_



## APPENDIX IV

### The Lumbar Isometric Flexion Exercise Regime

#### Postural Advice

This is adapted to suit each individual patient's problems, and based on the answers to the queries above. In general principles, however, the following is a basic guide.

#### (a) Sleeping

The fact that patients are so often woken at night by their backache and are usually very stiff in the early morning would suggest that poor sleeping positions are frequently responsible. Advice should be based on the principle that the patient should rest in a position that results in flexion rather than extension of the lumbar spine. The trunk should be fully supported and able to relax in this position, therefore a firm but supporting mattress should be used; ideally this should be of the firm interior-sprung type with a board placed underneath.

Many patients with chronic backache give a history a sleeping face down and, of course, in this position the lumbar spine is in a considerable degree of hyperextension, especially if they sleep on an old mattress with a deep sag! Ideally, the patient should change to an

alternative posture, but if it is difficult to sleep in any other position a small pillow can be placed under one hip so that the spine is not in complete lumbar extension (Fig. 1). Alternatively, a full-length pillow may be placed under one side to tilt the patient from the prone position (Fig. 2).

If the patient sleeps on his side with a bent knee, it may be of help to have a small cushion placed under the knee in order that it does not fall into an exaggerated adduction position and put a stretch on the back (Fig. 3). If the pain is very acute, a full-length pillow behind the back as well often enables the patient to relax more comfortably.

When the patient prefers to lie flat on the back it is advisable to tilt the head pillows into a wedge position so that the shoulders are supported sufficiently; the back then automatically takes a flexed position (Fig. 4a). If the patient lies quite flat, as is often recommended, the lumbar spine frequently assumes a position of hyperextension (Fig. 4b).

The patient should be advised that if he wakes up during the night, it would be useful for him to curl up with his knees on his chest, and his head flexed forward, and 'stretch the lumbar spine' before resuming the sleeping position (Fig. 5). It is usually not advisable for patients to carry out a great many exercises first thing in the morning if the back is very stiff.

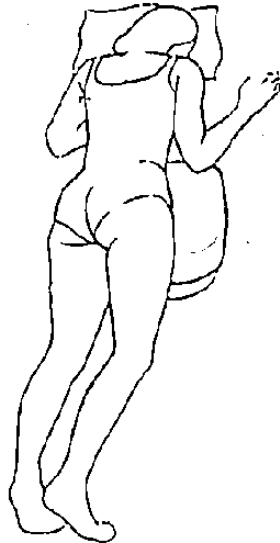


FIG. 1: Forward sleeping position with a small pillow under one hip to reduce lumbar extension

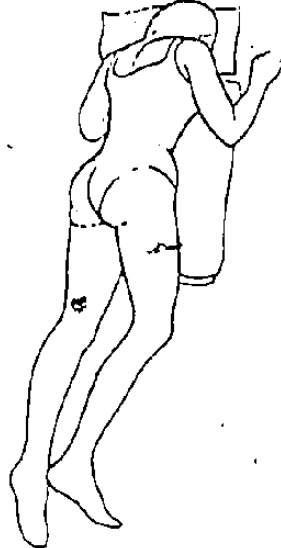


FIG. 2: Alternative forward sleeping position with a long pillow under one side to prevent lumbar extension

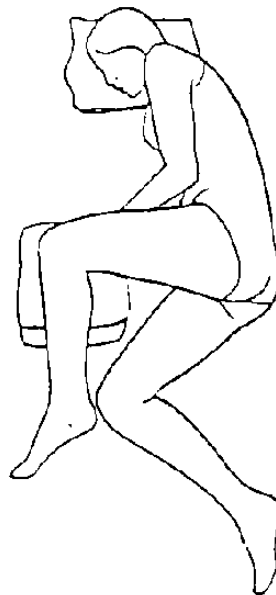


FIG. 3: Side sleeping position with pillow under one knee to prevent lumbar rotation and extension



FIG. 4a: Correct position of lying on the back with pillows positioned to eliminate lumbar lordosis



FIG. 4b: Uncorrected position of lying on the back



FIG. 5: Position to be adopted to relieve backache

Local heat, either with a hot-water bottle (which has the advantage of 'moulding' itself to the area, and thus giving some support) or electric blanket, may be prescribed and this is especially useful before getting up in the morning, as it helps the patient to relax.

(b) Sitting

The patient should be taught to relax with a flexed lumbar spine when sitting in a chair. Many patients with backache tend to place a pillow behind the lumbar curve and so exaggerate it. This should be discouraged and the patient should be advised to try to make a point of contact with the chair in the dorsal region and to slide his pelvis forwards at the same time, flexing the knees and supporting the feet on a stool if this is practical (Fig. 6). At home, a comfortable position is to sit sideways in a large armchair with the knees over the arm of the chair. If the patient likes sitting on the floor, he should be told to round the lumbar spine and bend the knees up rather than sit bolt upright.

(c) Standing

Standing still does not in itself usually result in immediate backache but may do so after a variable time. The patient must be taught to correct his posture in this position with the lumbar isometric flexion exercise and to contract the abdominal muscles as

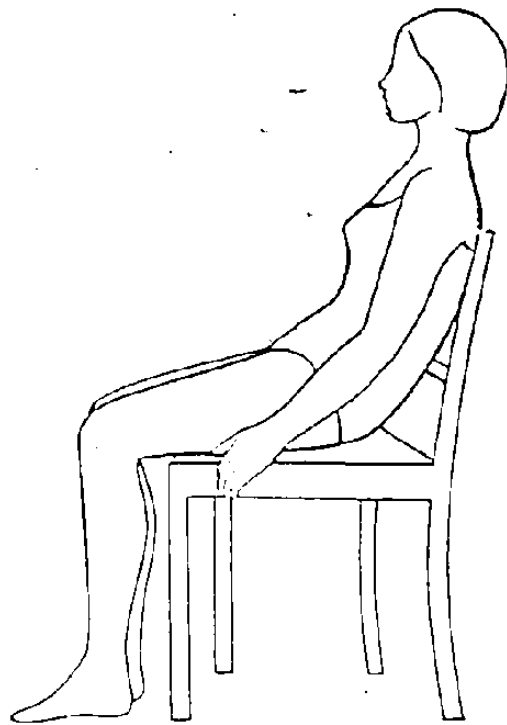


FIG. 6. To show correct position with elimination of lumbar lordosis

much as possible, constantly trying to 'flatten' the lumbar spine. If a patient has to stand for any length of time, it may be more comfortable for him to have one foot raised on a support, as it is when possible to 'round' the back more easily (Fig. 7).

(d) Working

One of the most difficult positions for a patient with a chronic backache to maintain is in slight flexion, the position adopted when vacuum cleaning, washing, making beds, etc. It is at this point that maximum muscle power is needed to maintain the position. Therefore it is advisable to eliminate completely the necessity of working in this difficult posture. This may be achieved by the usual methods of raising the height of washing-up bowls in the sink, or the work-table or bench. The same applies to typing, sewing, or performing any machine work; it is important to ensure that the patient is close to the work by setting the chair well into the desk or bench. If work must be carried out on or near the floor, it is more comfortable to be on all fours, provided the back is not allowed to 'sag'.

The well-established principle of bending the knees and getting close to the work should be observed as far as possible. If it becomes necessary to bend over, as is sometimes unavoidable with a heavy weight, the abdominal muscles should be strongly contracted, the lumbar spine flexed, and this position held during the lifting period; the leg



FIG. 7 Standing position with one foot raised to  
correct the lumbar lordosis



muscles should be strong in order to do much of the work. When small children are to be lifted, they should be held close to the patient while the abdomen is braced. It is also less strain to hold a child with its legs and arms round the mother rather than away from the body in a cradle fashion.

At all times during the working day, the patient should be encouraged to practise lumbar isometric flexion control, and flatten out the extensor lumbar curve by bracing the abdomen strongly. This may be illustrated to the patient with drawings, or by showing the patient an articulated spine, which does help to present a clear picture of the movement.

#### Exercise Techniques

##### (a) Lying Position (Fig. 8a and 8b)

The patient adopts the 'crook lying' position (on the back, with two or three pillows in a wedge shape under the head and shoulders, and one pillow under the knee). The exercise is taught in four stages.

1. The patient is asked to contract the abdominal muscles as hard as possible (pulling the umbilicus in towards the spine); then relax.

2. The patient then contracts the glutei; then relaxes.

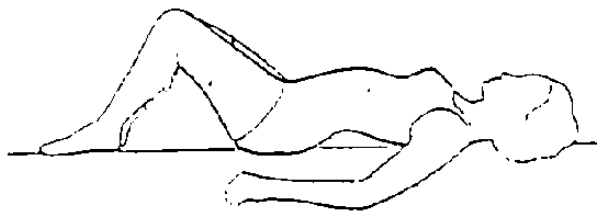


FIG. 8a Lumbar isometric flexion exercise to demonstrate the position before and after correction in crook lying

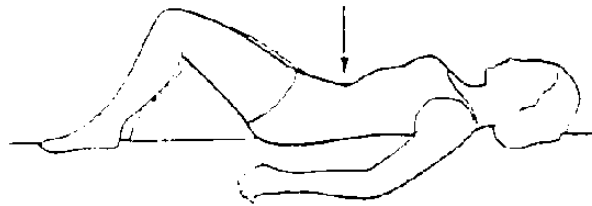


FIG. 8b Lumbar isometric flexion exercise to demonstrate the position before and after correction in crook lying

25

3. The abdominal and gluetal contractions are combined, thus producing a pelvic tilt with flexion of the lumbar spine.

4. The patient should then contract the hip adductors and the pelvic floor.

When the patient has mastered the above stages, the contractions should be held at a maximum for as long as possible (initially, patients find it very difficult to manage more than about five seconds, but this period should be gradually increased to about 15 seconds to complete the exercise). The exercise should be progressed by increasing the duration of the contraction and increasing the number of times the exercise is carried out, to a maximum of about 15 times. To start with, it is not usually possible for patients to breathe normally when contracting the abdominal muscles at a maximum, but as they become accustomed to the exercises they can usually be taught to do so.

(b) Standing Position (Fig. 9)

The same exercise is taught in the standing position. It does not matter if the patient adopts a posture with round shoulders and flexed knees to start with, as this may be corrected later. Once again, the exercise repeated up to 15 times, and subsequently as many times during everyday life as possible.

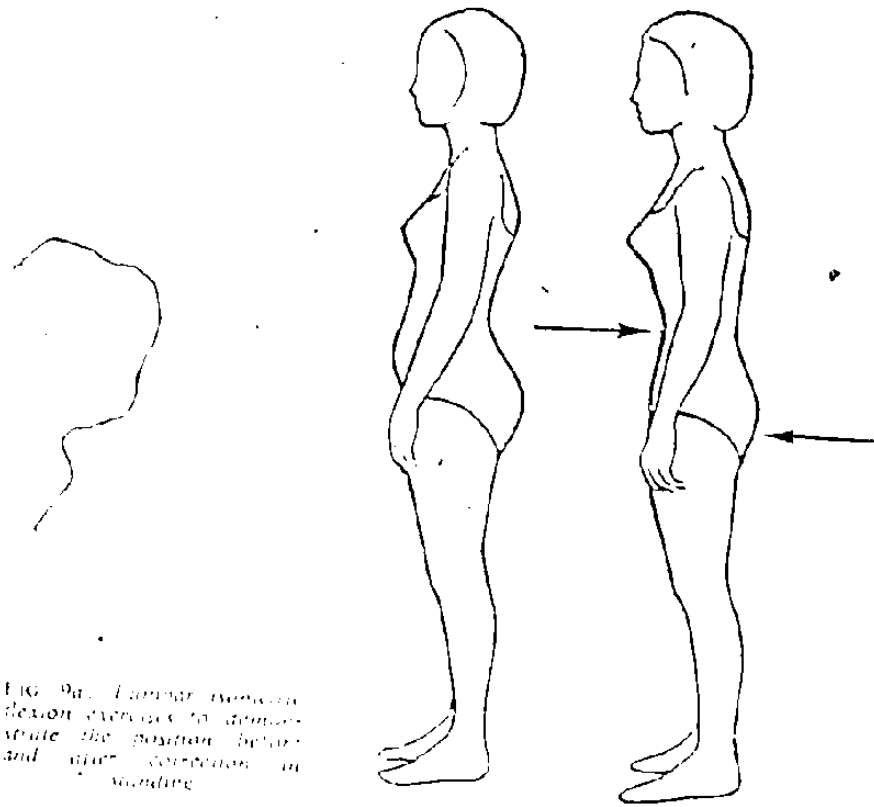


FIG. 9a. Lumbar motion  
flexion exercises to demon-  
strate the position before  
and after correction in  
standing

(c) Walking

As the patient becomes more proficient at the above two exercises, he should be encouraged to carry them out when walking, adopting the same principles.

## APPENDIX V

### Education Package

This will be developed in the form of a slide-tape show which can be operated by the patient. It should take no more than 10 minutes to complete. Subject material is derived from a review of the literature, but it relies heavily on Bergquist-Ullman (3) and Nachemson papers (54,58). In addition, the current physio-educational slide-tape show at McMaster has been reviewed. This show will contain the following elements:

- 1) several slides to show the anatomy and function of the back.
- 2) slides to show the most restful positions during sleep (the semi-Fowler position).
- 3) slide to show the problem with sleeping in the prone position.
- 4) slide on the function of muscles and their influences on the back.
- 5) slide to encourage the use of the isometric abdominal muscle exercises not only during active physiotherapy times but during daily activities at home.
- 6) slide on the avoidance of certain movements and postures in daily life.

- 7) slide illustrating the point of view that straight standing is better than non-supportive sitting, and that in sitting the back should have a good lumbar support and hip and knee joints should be kept well flexed.
- 8) forward bending should be avoided as much as possible and especially for long periods of time.
- 9) lifting weights, great advantage from a mechanical point of view, is obtained by teaching the patient to use knee extensors.
- 11) slide showing the bad effect of coughing, straining and jumping.
- 12) some slides will encourage the patients to increase their physical activity during their leisure hours with special emphasis on starting any physical training in water because of the supportive effect which water contributes to the relief.

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Bergquist-Ullman reported similar recovery rates to the other two Swedish studies of approximately 70% within two months, but got quite a bit lower at one month recovery rate of 35% (3). During the year she observed patients 62% had one or more recurrences. No patient had more than six recurrences in a year. (see Table VIII) The median number of recurrences was 1.3.

Also noted was the time between recovery from the initial episode to the first recurrence of pain. A median time for this first recurrence was 63 days (see Table VIII).

They noted another interesting fact in that the duration of the recurrences was shorter than the duration of the initial episode.

In a randomized clinical trial of therapies in the United Kingdom, which showed no differences in outcomes between manipulation physiotherapy, corset or analgesic groups, 54% of the patients were better at three weeks and 75% were better at six weeks (20). A trend towards improvement was noted in the corset group at three months.

Recurrence rates were reported but, as only 57% of the original cohort was available, these figures are likely not reliable.

Sims-Williams reported the results of a randomized controlled trial of mobilization and manipulation for patients with low back pain (96). This was a double-blind controlled trial to compare

mobilization and manipulation against placebo physiotherapy. No differences were noted in the final analysis of the trial. Details were not available in the paper to assess the duration of symptoms but personal communication with the authors reveals that approximately 50% were better at one month in both the treated and controls (97).

Finally, in two articles from general practice in England Dillon and Barker report on back studies in general practice (1,19). Unfortunately, Dillon's measure of the duration of the attack was the time between the first and the last office visit. This would underestimate the duration of the time. He obtained a figure of 84% of the patients better by four weeks time using this method. He did find that unlike all Swedish studies there was no significant variation in the duration of the attack by age (although there was a trend of 33% for patients under 30, 38% for those age 30-59, and 41% for those age 60). Finally, he reported that if there was objective evidence of nerve root pressure, the attack lasted significantly longer than if there was not.

Barker, in his survey of pain in the back and leg in general practice, reported that half his patients consulted only once and the others consulted twice or three times (1). Although the survey lasted two years, it is not possible to work out the recurrence rate in the manner in which this data is reported.

In the U.S.A. Greenfield reported 68.5% improvement within five weeks, with a 19% relapse rate (38). These figures come from 419 patients who attended a walk-in clinic at Kaiser Permanente in California.

Duration of back symptoms, of course, varies depending upon the source. In the case of industrial populations with evidence of disc protrusion approximately 39% of men are back to work within four weeks (4).

### 3.13 PERMANENT DISABILITY

In general practice, less than 1% of all back pain is due to disease which might cause permanent disability or death (1,19). Even in the area of low back pain in working men receiving Workmen's Compensation, 90% of patients are able to return to work within six weeks of their injury (103). White completed a fascinating study on 568 patients with discogenic low back pain who were interviewed every six months for four years following their discharge from the Workmen's Compensation. Two years would seem to be a critical period in prognosis, whether conservative or operative treatment was used. Those who regained ability to work by this time were likely to retain it; those who failed to do so were not likely to improve sufficiently in the following two years. Several other points are worth mentioning from this study in that achievement of a satisfactory status was not

influenced by radiological evidence of congenital or developmental abnormality, degenerative change or instability of the low back spine.

In addition, achieving satisfactory status was unrelated to occupation and age was seen to have little influence on progress.

### 3.14 AGE AND CLINICAL COURSE

In an interesting retrospective study done by an orthopedic surgeon, 259 patients over the age of 50 were assessed for etiology (31). Systemic disease, particularly cancer, was much more prevalent in the older group. It was demonstrated that simple screening consisting of an ESR and serum concentrations of alkaline phosphatase and calcium and phosphorus would identify all cases of unsuspected malignant disease. (At least one of the values was abnormal in every case).

### 3.15 RANDOMIZED CLINICAL TRIALS

A randomized clinical trial is the best design to investigate treatment effects. The key feature of this design is that the experimenter has control over which group, treatment or control, that the subject is assigned to. The subjects are assigned on the basis of a random number format, either from a random number table or generated on a random basis by a computer.

Although random allocation of patients to the groups in the trial is the essential feature of a randomized control trial, there are nevertheless a number of methodological standards which must be met by

the trial in order to strengthen the validity of its conclusions. A summary of these criteria has been discussed by Sackett, and will be reviewed here (90).

#### 3.15.1 Criteria for inclusion into the trial:

The study must describe what types of patients have been included and other important factors about them such as their location and situation. This criterion allows future investigators to generalize results or set up similarly designed experiments in order to test the validity of the results.

Included in these criteria are the patients' description of who was included in the trial and who was excluded.

#### 3.15.2 Random allocation:

This feature avoids conscious or unconscious bias on the part of the experimenter in terms of which patient gets in what group. Stated in different terms it allows the group to be "comparable".

#### 3.15.3 Prognostic stratification:

The experimenter may know that certain sub-groups vary in their risk of the outcomes. For example, if it is known that smokers are a greater risk for the outcome, the investigator should stratify smokers before randomization procedure so that the treatment and the control groups have an equal number of smokers.

Prognostic stratification should be reserved for factors which are strongly related to the target outcomes, otherwise the investigator may get into a position where he is stratifying numerous mildly related

factors and during the analysis may find that he has so few numbers in his cells that his analysis is not accurate.

Patients, of course, who enter the trial may have diseases in addition to the one which the trial is examining. One must make sure, for example, in a low back pain trial that patients do not have non-related muscular skeletal disease which could affect their participation or assessment.

\* Sometimes these co-morbid conditions may have a very strong influence on the outcome and so must either be handled by prognostic stratification or exclusion from the trial.

Finally, it is possible to do prognostic stratification during the analysis stage in certain circumstances (30). This likely should be reserved for situations where the investigator finds a confounding factor after completing his trial and wishes to distribute it equally between the two groups during his analysis. The investigator takes the risk here that he can in fact balance the two groups with the sample which has occurred in his particular trial.

#### 3.15.4 Description of the Therapeutic Manoeuvre:

In some ways this is similar to the criteria for inclusion in the trial in that the investigator must present enough detail of his manoeuvre, to allow readers to replicate the trial if they wish to.

#### 3.15.5 Compliance:

This issue has been ignored by medical designs for many years and is critical in the assessment of any trial. One must know

how well each of the groups followed the treatments given them in order to assess properly the results of the trial.

#### 3.15.6 Co-Intervention:

This term means that the experimentors must insure that both the controls and the group receiving the intervention have equal attention paid to them throughout the trial. Any additional therapeutic or diagnostic procedure applied to one group and not the other might effect and falsify the results.

#### 3.15.7 Contamination:

This is an attempt to minimize the control group getting the same or a related therapeutic manouevre as the treatment group in some form of external source. For example, in the back pain trial patients, of course, can go to osteopaths or chiropractors and receive related therapeutic manouevres.

#### 3.15.8 Diagnostic Criteria:

Whatever measurements the experimenter is using for the outcome should be consistent and reproduceable. This allows other investigators to use these outcome measures in other trials.

#### 3.15.9 Total Mortality Reporting:

It is important to report all causes of mortality in an experiment which uses this as one of the end points. This is to prevent the conclusion that although the treated group had fewer mortalities for one reason it increased the mortality of the same group through another mechanism.

As Sackett states, it is unlikely that any randomized trial will fully fulfil all these nine standards, but each trial should be assessed using these criteria to determine whether it has been given the best design within the limitations of design or the experimental setting.

### 3.16 TREATMENT (TABLE X)

A wide variety of treatments are available with the objectives of reducing or eliminating the patient's pain and returning him or her to normal daily activities. In line with the design of this thesis, which compares medical therapies, surgical therapies will not be commented upon in as much detail.

In general, the best efforts at trying to elicit which therapies are the most effective, come from the Scandanavian and British literature. These countries have been especially strong in trying to assess the effectiveness of traction, massage, mobilization, manipulation, and exercises.

#### 3.16.1 Traction:

Two trials in traction will be reported. The first one done by Lindstrom in 1970, with selected patients from an orthopedic out-patient clinic who had had back pain plus sciatic pain for more than one month's duration (60). People with obvious disc prolapse were excluded. Sixty-two patients were randomized into three treatment



TABLE X

LOW BACK PAIN - TRIALS OF THERAPIES

AUTHOR/ REFERENCE	SOURCE OF SAMPLE	RESULTS	STATISTICAL SIGNIFICANCE OR TRENDS	MAIN METHODOLOGICAL PROBLEMS
H. Sims-Williams (96) R.C.T. (N=94)	Patient's G.P. had requested x-rays.	ONE MONTH: Active physiotherapy and (mobilization and manipulation). (Maitland Tech- nique) and traction, better than placebo physiotherapy.	$\chi^2 = 3.56$ $0.01 > P > 0.05$	1) Open ended exclusion criteria available to physiotherapist. 2) No justification for sample size. 3) Subjective assessment of pain. 4) Postal questionnaire used as assessment at 12 months. No comments on reliability or validity. 5) No comments on compliance, co-morbidity, co-intervention or contamination.
D.P. Evans et al (27) Cross-over (N=32)	rheumatology clinic	THREE & TWELVE MONTHS:  Patients given rotational manipulation (3 times a wk.) Group receiving therapy first, better at day 21.	No statistical differences. No trends.  at 4 weeks  $P < 0.05$ Wilcoxin test for pair differences	1) Subjective assessment of pain. 2) No sample size justification.  3) No comments on compliance, co-morbidity, co-intervention or contamination.
Doran et al (20) R.C.T. (N=456)	rheumatology clinic	No differences between 4 groups: manipulation, physiotherapy, corset or analgesics.	No statistical differences. At 3 months, trend to corset. (83% vs 65% vs 74% vs 76%)	1) Overly rigid exclusion criteria. 2) Multicentered trial at tertiary care level subject to referral bias, Berkeson's bias. 3) No standardization of manipulations or physiotherapy. 4) High drop out rate. 40 out of 68 by three weeks. 5) Total sample down to 75% at six weeks 6) Questionnaires: reliability or validity not stated.

TABLE X

## LOW BACK PAIN - TRIALS OF THERAPIES (continued)

AUTHOR/ REFERENCE	SOURCE OF SAMPLE	RESULTS	STATISTICAL SIGNIFICANCE OR TRENDS	MAIN METHODOLOGICAL PROBLEMS
Coyer (13) R.C.T. (N=146)	Unknown	Manipulation (Cyrilax method) better than bed rest and analgesics.	Not done by Coyer. Completed by author (Gilbert) $P=0.006$ at 3 wk. period. But $P=0.33$ when 16 patients drop out in the bed rest group counted as successes.	1) Poorly defined exclusion-inclusion criteria. 2) Not a true random allocation ("alternate"). 3) No statistical analysis. 4) No comments on compliance with bed rest.
P. Ilume Kendall (54, 55) R.C.T. (N=47)	Physical Medicine patients.	Isometric exer- cises better than mobilizing or extensor exercises.	Author states statistically significant difference, but no value given.	1) Small sample size with no justification. 2) Exclusion criteria not stated. 3) Subjective outcomes.
J.R. Glover et al (37) R.C.T. (N=84)	Factory workers in U.K.	No difference between rotational manipulation (15 min.) and placebo diathermy.	Trend: patients, in whom first attack lasted less than 7 days at the time of treatment, had less subjective pain with manipulation.	1) A unusual exclusion criteria leading to severe sample depletion (200-84). 2) No sample size justification. 3) All outcomes subjective. 4) No data on compliance, co-morbidity, co-intervention.
Lindstrom et al (60) R.C.T. (N=62)	Orthopedic clinic	A combination of intermittent traction, isometric exercises of abdominal and hip extensors is better than a combination of hot packs, massage and mobilizing and strengthening exercises. It is also better than hot packs and rest.	$\chi^2=13.70$ $P<0.01$	1) Improper selection: orthopedic surgeons choice cases from their clinics. 2) Possible problem with easily broken code procedure. 3) Subjective outcomes. 4) No sample size justification. Small numbers in each cell.

TABLE X  
 LOW BACK PAIN - TRIALS OF THERAPIES (continued)

AUTHOR/ REFERENCE	SOURCE OF SAMPLE	RESULTS	STATISTICAL SIGNIFICANCE OR TRENDS	MAIN METHODOLOGICAL PROBLEMS
H. Bergquist- Ullman et al (3) R.C.T. (N=217)	Volvo clerks and workers.	Back school educational program and combined physio- therapy (Cyrilax and Janda methods; stabilization, gapping, articula- tion, stretching) were better than placebo shortwave.	Statistical significance for: a) sick-leave duration. b) duration of symptoms from first treatment.  NO statistical differences for: a) pain index (no trend) b) recurrences (Trend in favour of placebo).	1) No sample size justification. 2) Compliance, co-morbidity, co-intervention and contamination not assessed.
H. Weber (101) R.C.T. (N=72)	Orthopedic clinic.	"Tru-trac" traction is no better than simulated traction.	No statistical difference.	1) Only English abstract from Norwegian available.
J. Baldwin (73) R.C.T. (N=180)	General population in Scarborough	Mobilization no better than traction. Both had educational package.	No statistical difference. No trends.	1) Attrition rate 26%. 2) Majority of outcomes subjective.

groups, conventional physiotherapy, (hot packs, massage, mobilizing and strengthening exercise of the spine) control group of hot packs and rest and thirdly intermittent pelvic traction, isometric muscle exercises and immobilization. Results according to the author show that the pelvic traction and isometric exercises was the best treatment and reached statistical significance. The problem with the trial is that later on in the results section the author analyzing "the different methods separately" found there was no significant difference between the control and the traction group. In fact it is difficult to draw conclusions from the study because the actual numbers spread amongst the three treatment groups are very small and in fact in four places he had zero numbers in some of the cells.

In 1973, Webber placed 72 patients who had evidence of back pain and nerve root irritation into one of two groups (101). Either Tru-Trac intermittent traction, or a simulated traction. Results show there was no clear difference between the two groups. Most patients in both groups described the traction as pleasant, which may well explain some of the popularity of this treatment. A randomized control trial between mobilization and traction by Baldwin failed to show any differences between treatments (73).

Nachemson has shown experimentally that the pressure of the nucleus of the disc falls during the traction in the supine position by 25% (77). However, this experiment was done with normal subjects

with normal discs, and the comparison with the disease situation is questionable. In fact the concept that a protrusion will simply slide back spontaneously because of an increased space between the vertebrae, or that reduced pressure to the disc will have a suction effect, seems too mechanical in light of the complex pathology of disc degeneration.

### 3.16.2 Physiotherapy:

MANIPULATION - perhaps no area of therapy has caused as much controversy as this particular one. This is because several different disciplines use the method called manipulation and there is a long-standing animosity amongst them. Part of the problem results in the fact that there are many "manipulation schools" in the world. One is run by osteopaths, one by chiropractors, and physiotherapists have several of their own. All these used different methods of applying twisting, stretching and bending forces to the lumbar spine. The unproven theory behind most of these manouevres is that a "locked" and painful segment should be loosened. A diagnosis of this decreased segmental mobility was made by careful palpation through more or less thick layers of soft tissue. Various better designed trials using manipulation will be reviewed next. One cannot help but come away with the conclusion that if the clinical effect of these methods is superior it hasn't been shown in a form which would be reasonable for most clinicians who have a critical attitude.

In 1955 the British Medical Journal reported on a controlled study treating low back pain with manipulation in one group and bed rest and analgesics in the other group (13). The method of manipulation was that of Cyriax. There are a number of methodological problems with this study, the first one being that there was no randomization of patients to each treatment group which could form a considerable bias. Secondly, of the original two groups the control group lost 16 patients and in the analysis it was assumed that none of these patients became well (the correct assumption would be that they all became well). Nevertheless, the author went on to say that manipulation was more effective, although when his results are reanalysed (by me), including adding the 16 patients in, there is no significant P value obtained.

Glover in 1960 described a back syndrome where there was a clearly defined area of hyperesthesia and a local tender spot associated with the hyperesthesia (36). The final two points of the syndrome were dull ache in the same area and a limitation of movement by pain. After selecting the cases out of the engineering firm he manipulated the low back until a definite click was heard and claimed 89% success rate.

In 1974, Glover conducted a therapeutic trial in engineering works in England in which he randomly allocated patients to one lumbar rotational manipulation session of fifteen minutes followed by four

daily detuned short-wave diathermy sessions (37). The control group was given the detuned short-wave diathermy only. At the end of seven days there was no demonstrable difference between the two groups. The author felt in retrospect that he should have given more manipulation sessions.

In 1975 Doran released the results of a multicentred trial of 456 patients who had been randomly allocated to four treatments - manipulation, physiotherapy, corset, or analgesics (20). Conclusions were that there were never any important differences among the four groups of patients. However, he managed to keep track of only 73% of the sample to three months and by one year had only 57% of his sample. The technique of manipulation was at the discretion of the manipulator. A minimum of two treatments per week was given with an average of six treatments per patient. There was a barrage of letters to the editor. Cyriax himself wrote in complaining that the wrong type of patients were studied (15). The B.A.M. (British Association of Manipulative Medicine) group were particularly incensed with the B.A.R.R. (British Association of Rheumatology and Rehabilitation) trial because they felt that the B.A.M. members had not been given proper control over the admission of the patients to the trial (24). This appears to be one of the main points of controversy; one group claiming there are definite criteria for doing manipulation and insisting that these be used prior to the start of the trial.

In 1978 Sims-Williams studied 94 patients in a randomized control trial which included random allocation to active or placebo physiotherapy (96). Patients were selected from cases that the general practitioner had requested x-rays from at the local hospitals.

The placebo group received microwave radiation at the lowest possible setting while the treatment group received traction, mobilization and manipulation (by the Maitland type) and abdominal and spinal exercises. Results at the one month assessment were of borderline significance except that the treatment group did get more people back to light work. However, by three months there were no statistical differences and no trends between the groups and at one year there still were no differences between the groups.

This trial received a letter from the Osteopathic Medical Association stating that you cannot treat patients with only one system of manipulation (16). The author went on to say that even for the same patient he often uses the Oregon or hold system and if this fails, the Hoover for one cannot just rely on the Maitland system alone. This letter serves to illustrate just how complex the manipulation trial would have to be in order to satisfy many of the critics.

There are, of course, critics of manipulative treatments and authors have reported side effects such as increasing pain secondary to manipulation. Perhaps the most serious side effect reported were two



cases of massive posterior sequestration of the lumbar discs resulting in paresis to the patients (46).

Evans conducted a cross-over trial comparing a rotational thrust manipulation with distraction both to the left and to the right (27). Thirty-two patients with chronic low back pain were treated three times at weekly intervals by this manipulation followed by a three week rest period. The second group had the rest period first followed by the manipulation treatment. Codeine was given to both groups. The results stated that patients who had the manipulation first had significantly less pain at the end of the four week period. However, the results are broken down into so many different groups and variations that it is difficult to follow the authors paper. At one point the author ~~did~~ concede that the first week of manipulation treatment was more painful than the corresponding week in the control group. This comment has been noted before in manipulation trials - that the treatment itself is painful.

### 3.16.3 Chiropractic Treatment:

"Ever since 1895, when D.D. Palmer, erstwhile 'the magnetic healer' and founder of the chiropractic movement, claimed to have restored a deaf janitor's hearing by manipulation of the spine, organized medicine has considered chiropractics a form of quackery and campaigned against its acceptance" (88). Chiropractors insist that it is far more than simply a form of physiotherapy for back pain. It

claims to be an alternative system of primary health care - a scientific profession that is at least as competent as medicine in the diagnosis and non-surgical treatment of most human ailments.

There is a scarcity of scientific data on the validity of chiropractic theory and the effectiveness of chiropractic therapy. In fact the first experimental study of the basis for the theory for vertebral manipulation to be published in a recognized journal appears in 1973 (14). However, a group of general practitioners reviewed the results of approximately 122 cases of back pain seen by a chiropractor and 110 cases seen by general physicians in the area of Salt Lake City, U.S.A. (51). Results by two measures of outcome, patients' perception of improvement and patient satisfaction, showed that the chiropractors were as effective with the patients as were the physicians.

The report of the Working Group on Back Pain, chaired by Archie Cochrane, reviewed the chiropractic literature and calls for well designed comparative trials particularly of manipulative treatment which represents chiropractors, osteopaths and acupuncturists (104).

#### 3.16.4 Acupuncture:

The Working Group on Back Pain reviewed the world literature on acupuncture as a treatment for back pain and concluded that it too must participate in rigorous trials in order to assess its effectiveness (104).

Although there is extensive literature on acupuncture in acupuncture journals, it is rarely mentioned as a form of therapy in any medical journal.

Two Canadian studies have been reported using acupuncture in low back pain. The first by Rapson was presented at the OMA Section of Acupuncture and showed the results of 91 patients treated by this method (87). However, the study lacks rigor as there were no controls. The other study also had no controls but like the first one concluded that acupuncture was in fact an effective method for low back pain (25).

#### 3.16.5 Bed Rest:

There have been no randomized clinical trials using bed rest as one of the forms of therapy.

The advice for bed rest is based on empirical evidence that people with low back pain feel better when they are not moving. It has also been established by the same evidence that if you are lifting something heavy when you have back pain, you are likely to feel worse (63). Perhaps a second reason for bed rest is that you can't be lifting very much if you are in bed. Likely the third source for bed rest comes from the treatment of prolapsed lumbar discs (63). For years the surgeons have used this as their main conservative therapy prior to operating on the patient. The general rule here is that if

a patient is not better after two or three weeks of complete bed rest a myelogram and possibly surgical intervention are needed.

Several comments should be made regarding the basis for this use of bed rest. The fact that some patients with low back pain feel better in bed does not necessarily mean that the bed rest will make them better sooner. It is possible that if one could relieve their pain with analgesics and have them somewhat mobile that they would get better faster than a comparable group who were placed in bed. The main concern of physicians that patients might lift something during an episode of back pain and thus advising them to go to bed seems rather extreme and it seems more reasonable to advise a patient not to lift any heavy objects.

Finally, even if bed rest is proven to be important in the treatment of prolapsed discs, it must be tried in a wider range of back conditions.

Some trials have included bed rest, usually with analgesics as a form of control group. Coyer used it as a control group against his manipulation of the lumbar spine (13). There were no differences between the groups at three weeks, and if his six week outcome was evaluated properly, counting his drop-outs, there were no differences between the two therapies at six weeks either. Unfortunately, there is no mention of the length of bed rest nor any evidence that the authors checked as to whether any patient was in fact resting.

A second study included three groups; mobilization exercises, traction and a control group treated with hot packs and rest only (60). Again no definitions or statement about compliance with the control group are presented.

Even, in an otherwise well designed randomized controlled trial, bed rest was not monitored (3).

#### 3.16.6 Exercises:

The most commonly prescribed remedies for patients with low back pain, at least by orthopedic surgeons and physical medicine doctors are various forms of physical exercise. Different flexion and extension exercises have been recommended in order to increase the mobility of the spine and the strength of the abdominal and back muscles. As was mentioned in the basic research section of this thesis, studies have been done looking at the effects of these exercises, and there are a number of control clinical trials using exercise as one of their treatment groups.

Nachemson and Elfstrom have shown that many of these exercises increase the load on the lumbar spine that it often reaches the magnitude as high as those measured in standing and leaning forward with weights in the hands (81, Figure 5)

With regard to disc pressure, isometric exercises seem to be less stressful (82). Two control studies have demonstrated that such exercises, alone or in combination with traction, give better clinical

results than ordinary flexion and extension programmes (60,54).

It remains to be shown that strong muscles protect the back from painful episodes.

In the one trial by Lindstrom, he had three treatment groups (60). One, a control group with hot packs and rest. The second group was what he called conventional therapy consisting of hot packs, massage and a combination of mobilizing and strengthening exercises. The third group contained the isometric exercises but also contained intermittent pelvic traction. In this study it was reported that the traction and isometric exercises were statistically significantly better, but one must be cautious because the numbers in some of the cells were extremely small and in fact in four cells there were zero numbers. However, this study taken with Kendall's study in which he used a double-blind randomized control trial on three forms of exercise, mobilizing exercises, isometric exercises and back strengthening exercises, show the best results were obtained in the isometric exercise group (54). In addition, one of the other interesting results reported was the number of patients made worse by the other two exercises. In the case of the mobilizing exercises two patients out of fourteen reported they were worse after the treatment and five patients out of fourteen on the back extensor exercises reported they were worse after treatment.

No evidence has been presented that subjects with low back pain possess particularly weak muscles, except when they have been kept off work for a long period of time (77). On the other hand it is known that in certain situations, i.e. while lifting and carrying heavy objects, the increase in the intra-abdominal and intrathoracic pressure from contraction of the abdominal and intercostal muscles will help to relieve some of the load on the lumbar spine (75). It should therefore be regarded as rational for patients in their rehabilitation programme after a long period of low back pain to perform isometric abdominal muscle exercises. Also in these patients, special preference should be given to the training of quadriceps muscles, as these take more load when lifting weights the correct way than the wrong way. (Figure V).

Kendall describes his use of lumbar isometric flexion exercises in detail in a paper reported in Physiotherapy (55). He comments on the possible mechanism by which these exercises could work. He states that in a large number of patients suffering from low back pain an accentuated lumbar lordosis with lax abdominal muscles is often noted. Isometric exercise when followed by the patient tends to correct this postural abnormality.

### 3.16.7 Back Education:

A number of authors have called for or included back pain

advice as a treatment for these patients. The underlying point appears to be that one can instruct the patient carefully to avoid certain movements and postures in daily life that were felt to increase the load on the back (17,82). From that point of view straight standing is better than unsupported sitting (82). In sitting, the back should have a good lumbar support and the hip and knee joints should be kept well flexed. Forward bending should be avoided as much as possible and especially for longer periods of time. When lifting weights, great advantage, from a mechanical point of view, is obtained by teaching a patient to avoid flexion of the back. He should be instructed to flex the knees and keep the spine as straight as possible so that when lifting he makes use of the knee extensors. From a clinical point of view, coughing, straining, and jumping, have been known to exaggerate the symptoms of back pain (48,47).

An educational programme similar to that described above was tested in a randomized trial by Berquist-Ullman against a control group of placebo short-wave treatment and another active treatment group, consisting of various forms of physiotherapy (3). The patients in the physiotherapy group had individualized exercises depending on the diagnosis by the physiotherapist. The treatments used by the physiotherapist were stabilization gapping, articulation, stretching, and static and dynamic exercises. The authors concluded that the back school or the physiotherapy were both superior to the placebo treatment



but the back school also reduced the absence from work significantly better than the combined physiotherapy.

### 3.16.8 Pain Relief:

Physicians generally offer pain relief to patients with back pain. There are minor drugs such as aspirin with or without codeine, but an unknown number of certain anti-inflammatory drugs are also dispensed, usually on this continent in the form of Indomethacin. Two trials have been reported using Indomethacin in low back pain. In the first one there was a positive response with most of the patients that had been subdivided into four groups (7). Unfortunately, there were no control groups. In 1974 a double-blind trial was conducted with Indomethacin against Prinalgin (50). The results show that there was no difference at the end of one week between the two drugs.

### 3.16.9 Aggressive or Invasive Treatments:

There are a number of treatments in this area such as chemonucleolysis, acupuncture, percutaneous radiofrequency denervation of the facet joints, steroid injections; all have claimed good or excellent results, however, there have been no randomized clinical trials completed (29,95,99).

### 3.17. SUMMARY OF TREATMENTS

The evidence on most approaches to therapy is unsatisfactory and often conflicting, largely because many forms of therapy have not

been evaluated in an acceptable and scientific manner. It could be successfully argued that the final answer is not in any particular form of treatment. However, it does appear that in the area of muscle exercises in the early form of treatment and certainly in the rehabilitative part that isometric exercises have a place. One well designed study did show that back education in the form of teaching patients how to adjust and work with their backache in their normal daily activities was as equal or better than physiotherapy and was better than the control group.

A few reasonably well designed studies have showed some benefit from various forms of manipulation. However, there is an unsettling trend in some of them in which the patients are often made worse before they are made better, and many different schools have developed making studies very difficult.

Bed rest as a form of treatment has received only superficial attention in any trial and has not been subjected to any randomized control trial.

#### 4. RESEARCH DESIGN (Table XI)

The Question: Does the addition of physiotherapy or bed rest, singly or in combination, to patients receiving analgesics for low back pain improve clinical outcomes?

##### 4.1 INTRODUCTION

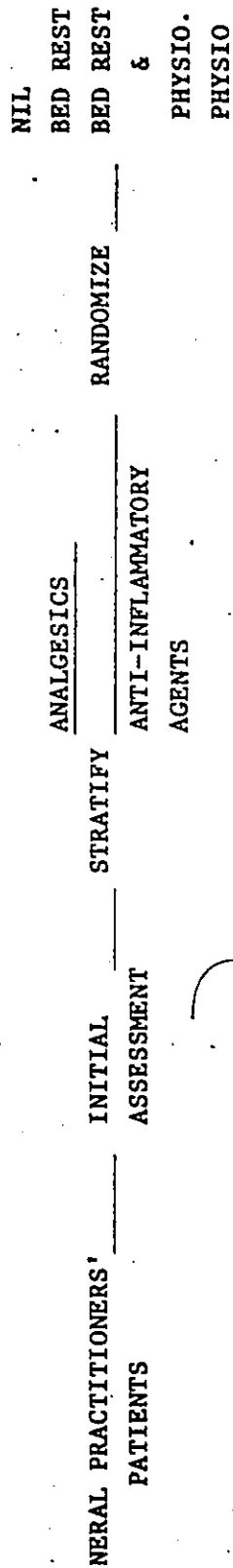
A group of patients suffering from low back pain who present themselves to their local general practitioner will be entered into the randomized clinical trial. This trial will evaluate four groups: physiotherapy-bedrest, physiotherapy alone, bedrest alone and nothing (2 x 2 Factorial Design). All patients will be given pain-relieving medicine; and objective outcomes will be measured (Table XII).

After the patients have passed the inclusion and exclusion criteria they will be stratified according to whether the general practitioner has placed them on regular analgesics or anti-inflammatory agents. They will then have a base-line assessment and be randomized into one of the four groups.

At one and three months, assessment for outcomes will be carried out by an observer who is blind to which treatment group the patients are in. Outcomes will consist of change in patients' report of change in range of motion of the back and in straight leg raising,

TABLE XIII

FLOW OF DIAGRAM OF TRIAL



OUTCOMES

1. Pain relief
2. Normal daily activities.
3. Return to work.
4. Status of back.
5. Relapse.

TABLE XII

TABLE OF FACTORIAL DESIGN

Bed Rest

		Yes	No
PHYSIOTHERAPY	Yes	Bed rest and	physiotherapy
EDUCATIONAL		physiotherapy	package
PACKAGE	No	Bed rest	NIL

\* each group gets analgesics

return to work or a return to normal daily activities and finally the time of the first recurrence of back pain.

4.2. METHODS OF PROCEDURE (see Table X)

4.2.1 Patient source:

All potential candidates for the study sample will be identified by the general practitioners of five group practices in the City of Hamilton.

4.2.2 Patient selection:

- A) assessment - patients with low back pain will undergo base-line assessment by means of a questionnaire administered by the receptionists and a physical examination done by their own general practitioner.

The questionnaire will assess the following:

- i) normal demographic data on the patient

(Appendix I)

- ii) characteristics of the pain (Appendix I)

- iii) daily activities questionnaire (Appendix II)

4.3 INCLUSION CRITERIA

Any patient who presents to his or her general practitioner's office with low back pain\* and who has met the following criteria.

- 1) Pain localized to the lumbosacral area, with or without radiation to the thigh.
- 2) Duration of pain before entry to the trial, not longer than four weeks.
- 3) A pain-free interval six months before the onset of the current episode.

4.4 EXCLUSION CRITERIA

- 1) Any patient who has had a treatment that involves the lumbosacral vertebral column in an invasive procedure.
- 2) Spondylolisthesis
- 3) Infections of the vertebral column.
- 4) Tumors, primary or secondary of the lumbosacral vertebral column.

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\* Definition of Low Back Pain: Pain between the twelfth thoracic spine and the last sacral spine. The pain may radiate into one or both buttock areas or to one or both thigh regions. The pain would be of sufficient severity to bring the patient to his or her general practitioner and to be interfering with the patient's normal daily activities. (Normal daily activities are defined by question 2 in Appendix II).

- 5) Ankylosing spondylitis: This disease can be diagnosed when the patient has four out of five of the criteria below (or number six and any other).
- i) low back pain of over three months duration, unrelieved by rest.
  - ii) pain and stiffness in thoracic cage.
  - iii) limited chest expansion.
  - iv) limited motion in the lumbar spine.
  - v) past or present evidence of iritis.
  - vi) bilateral radiographic sacroiliitis.
  - vii) radiographic syndesmophytosis.
- 6) Fractures of the vertebral column.
- 7) Patient has objective evidence of a prolapsed disc. (Any one or more objective neurological signs which would be compatible with a patient's history).
- 8) Any concurrent diseases which is active in the opinion of the patient's general practitioner, and likely to affect the patient during the trial.
- 9) Paget's disease.
- 10) Pregnancy.
- 11) All patients will have the following blood tests: ESR, Serum calcium and phosphorus, acid and alkaline phosphatase. These tests have been found to be highly



reliable in diagnosing neoplasms in patients with low back pain. An x-ray of the lumbosacral region will also be ordered on each patient (A-P and lateral views). If any one of these blood tests are positive the patient will be excluded from the study. Patients will be excluded from the study if the x-ray shows any of the exclusion conditions.

- These exclusion factors will not have a large effect on the sample size as they make up less than 4% of the types of back pain seen by general practitioners.

#### 4.5 ETHICAL CONSIDERATIONS

Those patients who fail to meet the inclusion criteria will be excluded from the trial but still will be offered treatment. Those who do meet the admission criteria will be informed of the full nature of the trial, any attendant risks that might be involved, and what would be expected of them if they chose to participate. The individuals involved in the study would have the right to withdraw from the study at any time without loss of care. They would remain free from assault and would be guaranteed confidentiality. Should the therapist treating the patient involved in the study decide at any time that the treatment is increasing the patient's symptoms the treatment will be discontinued and counted as a failure.

Eligible patients will be asked to sign a consent form (Appendix III). This consent form will outline the conditions of the trial and guarantee that the patient may quit the trial at any point without jeopardizing their future care.

#### 4.6 STRATIFICATION

Stratification prior to randomization in the trial would be important if one or more factors in the population other than the factor being examined in the trial could influence the outcome. Having reviewed the literature there do not appear to be any factors that fall into this category. Bergquist-Ullman (3) did give a reasonable historical explanation for stratifying patients on occupation and psychological traits. However the results of their trial when analyzed failed to show that occupation and psychological traits were major confounding factors.

The trial being designed deals with the largest single group of back pain sufferers, but has excluded ones known to have serious disease, such as cancer or prolapsed disc. Therefore, there is no need to stratify for those diseases. (See Exclusion Criteria)

Randomization, in itself, is a method of insuring comparability of groups should there be factors which are unknown to us at the present time.

The patients will likely all be offered some form of pain relief and/or anti-inflammatory drugs. This is going to be continued as this is the common treatment in general practice at the present time. Although there is no hard evidence that anti-inflammatory agents are more powerful than normal analgesics in the treatment of this type of patient in this trial, it is felt for clinical credibility that the patient should be stratified into the simple analgesic group or anti-inflammatory group.\*

4.7 DESCRIPTION OF THE THERAPEUTIC MANOEUVRE

Five groups of general practitioners will be sought to participate in this trial. A group of general practitioners will be defined as two or more physicians working in the same office.

Any patient presenting to his own family physician with the sole complaint of back pain meets the exclusion and inclusion criteria and will be admitted to the trial. History and physical examination will be performed on the patient by the patient's own family physician.

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\* Description of Anti-Inflammatory Drugs - A drug which has a higher potency than aspirin. e.g. phenylbutazone, Indomethacine or Codeine. Minor drugs include simple analgesics such as aspirin.

Because the presence of a second disease may markedly affect the ability of patients to participate or be assessed in this trial, only patients who currently only have one active disease, namely low back pain, will be admitted to the trial. If the patient has a chronic disease which is under good clinical control and in the opinion of the family physician is unlikely to change in the next four weeks, the patient will be accepted into the trial.

The history will not be standardized as the important data needed from the history will be obtained through the questionnaire described below.

Physical examination will also be left to the discretion of the physician with the exception of two areas. A) Range of motion of the back in flexion, B) straight leg raising.

One receptionist in each group who has previously been tested for ability to administer the McGill pain questionnaire will administer this and a modified health index questionnaire (modified from Chamber's) to each patient (8,68).

The receptionist will then dial a central number which will serve as a center for random assignments to one of the four treatment groups. The patient will either receive a physiotherapy educational package, or a physiotherapy education package plus bed rest, bed rest alone, or none of the treatments.